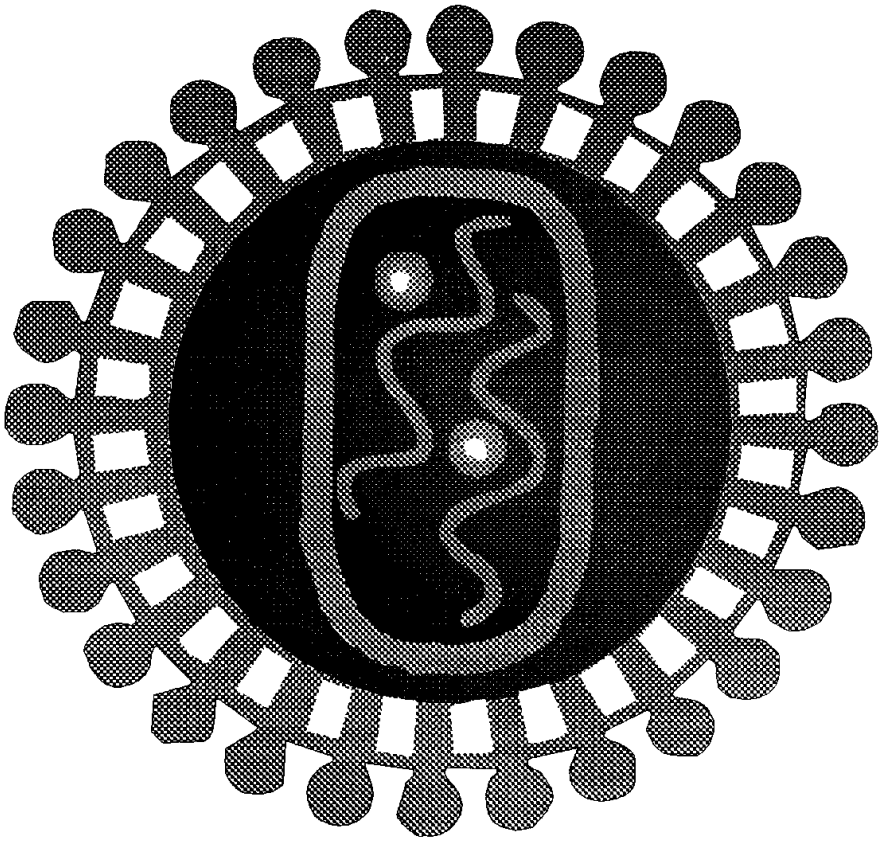
Results of the 1997 Retroviral Testing Survey Questionnaire Sent to Laboratories Participating in the Model Performance Evaluation Program



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

CENTERS FOR DISEASE CONTROL AND PREVENTION

Results of a 1997 Retroviral (human immunodeficiency virus type 1 and human T-lymphotropic virus types I and II) laboratory questionnaire survey mailed to laboratories participating in the Model Performance Evaluation Program, Centers for Disease Control and Prevention (CDC).

The production of this report was coordinated in CDC by:

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Introductory Comments on the Model Performance Evaluation Program 1997 Retroviral Questionnaire Survey Results

The Model Performance Evaluation Program (MPEP) retroviral questionnaire survey was mailed September 8, 1997, to 885 laboratories of which 708 (80%) responded. Of these 885 laboratories receiving the questionnaire, 732 were laboratories located in the United States (US) or US territories and 604 (82.5%) responded. The remaining 153 laboratories were located outside the US and 104 (68%) 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.

On pages 2 and 3, the number of laboratories enrolled in the MPEP by country, including the United States and Territories, reflects the enrollment as of August 13, 1997 and does not necessarily reflect the MPEP enrollment at the time this survey was mailed.

All parts of questions 6 and 7 were designed to reflect current regulatory requirements related to the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) as published in CFR 42 Part 493. These questions address the amendments related to the education and certification requirements of the laboratory director and supervisor. Questions 20 and 29 were designed to reflect the frequency with which external quality control samples are used and are also related to CLIA-88 regulations.

In question 11, more than 90% of the responses in the "Other" category were specimens described as oral fluid (transudate/saliva) and/or urine; therefore, these responses were subtracted from the "Other" category and presented as unique responses in the graphic. Similarly, in question 12, oral fluid (transudate/saliva) and/or urine were described in approximately 90% of the responses in the "Other" category; therefore, these responses were subtracted from the "Other" category and presented as unique responses in the graphic. Likewise, in question 20, the use of external quality controls with "Each New Kit Lot" was indicated for one or more test method by 52 laboratories; therefore, this category was presented as a unique response and removed from the "Other" category.

For questions 15a, 15b, and 24 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 (28 - 41%) and HTLV (18.5%) antibody. These various unique testing combinations are grouped as "Other Algorithms" in the tables reporting the responses to questions 15a (28.2%), 15b (40.6%), and 24 (18.5%).

In questions 16 and 24 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 22 and 31, 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.

Number of MPEP laboratories by country

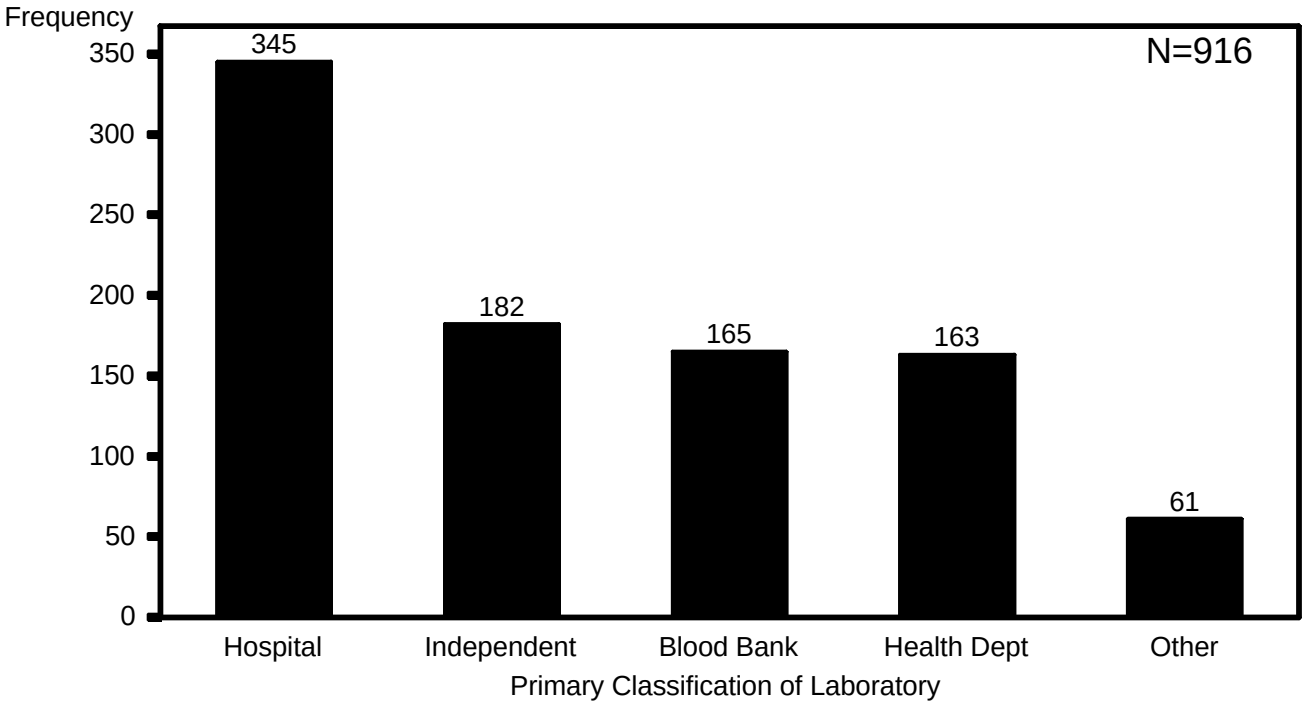
N = 916

Country	Number of Laboratories	Country	Number of Laboratories	Country	Number of Laboratories
Argentina	3	Honduras	2	Scotland	1
Australia	6	Hong Kong	2	Slovakia	1
Austria	3	Hungary	1	Slovenia (Yugoslavia)	1
Bahamas	1	India	2	South Africa	3
Barbados	1	Ireland	1	South Korea	1
Belgium	2	Israel	1	Spain	3
Bolivia	1	Italy	2	Sri Lanka	1
Brazil	4	Jamaica	1	St. Kitts/St. Nevis	1
Burkina Faso	1	Japan	2	Suriname	2
Canada	20	Kenya	1	Switzerland	3
Central African Republic	1	Malaysia	2	Taiwan	2
Chile	2	Malta	1	Tanzania	2
Colombia	1	Mexico	1	Thailand	5
Costa Rica	2	Morocco	1	Trinidad/Tobago	3
Cote d'Ivoire	2	Myanmar (Burma)	1	Turkey	1
Croatia	2	New Zealand	1	US Territory	25
Curacao, Netherlands Antilles	1	Nicaragua	1	Uganda, East Africa	2
Denmark	3	Nigeria	1	Ukraine	1
Dominican Republic	3	Norway	1	United Arab Emirates	3
Ecuador	1	Panama	1	United Kingdom	2
Egypt	1	Paraguay	1	United States	737
El Salvador	1	Peru	3	Uruguay	1
England	2	Philippines	2	Venezuela	3
Ethiopia	1	Portugal	1	Vietnam	1
France	1	Republic of Singapore	1	Western Samoa	1
Germany	4	Russia	1	Zambia	1
Guatemala	1	Saudi Arabia	3		

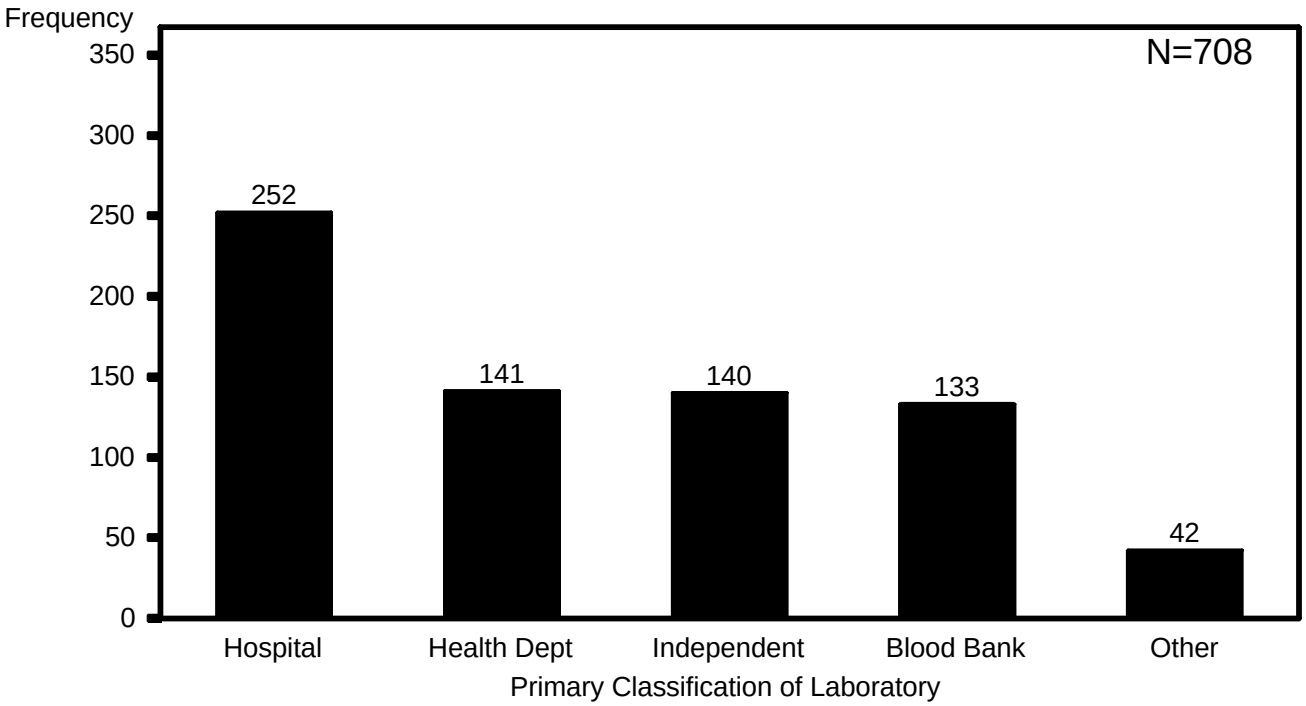
Number of MPEP Retroviral Laboratories in the United States and Territories

Primary Classification of MPEP laboratories in regard to Retroviral testing

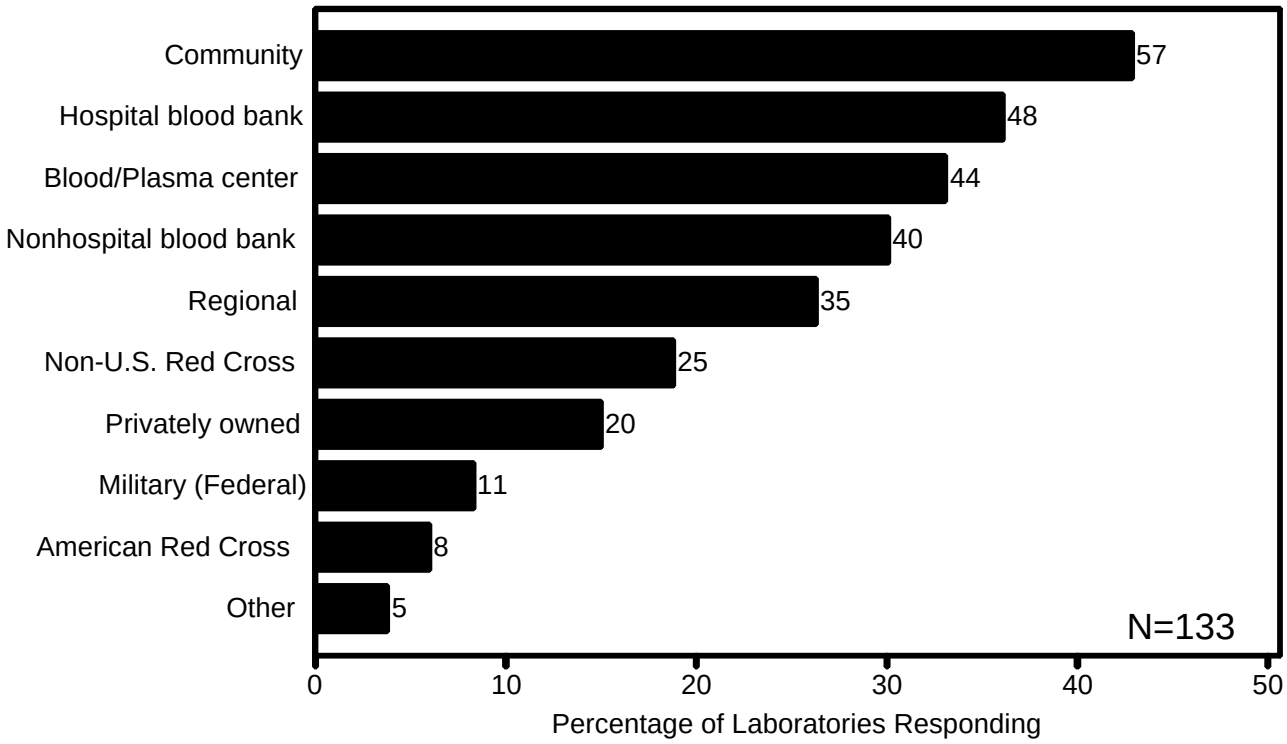
Total Number of Laboratories Enrolled in the Retroviral Program



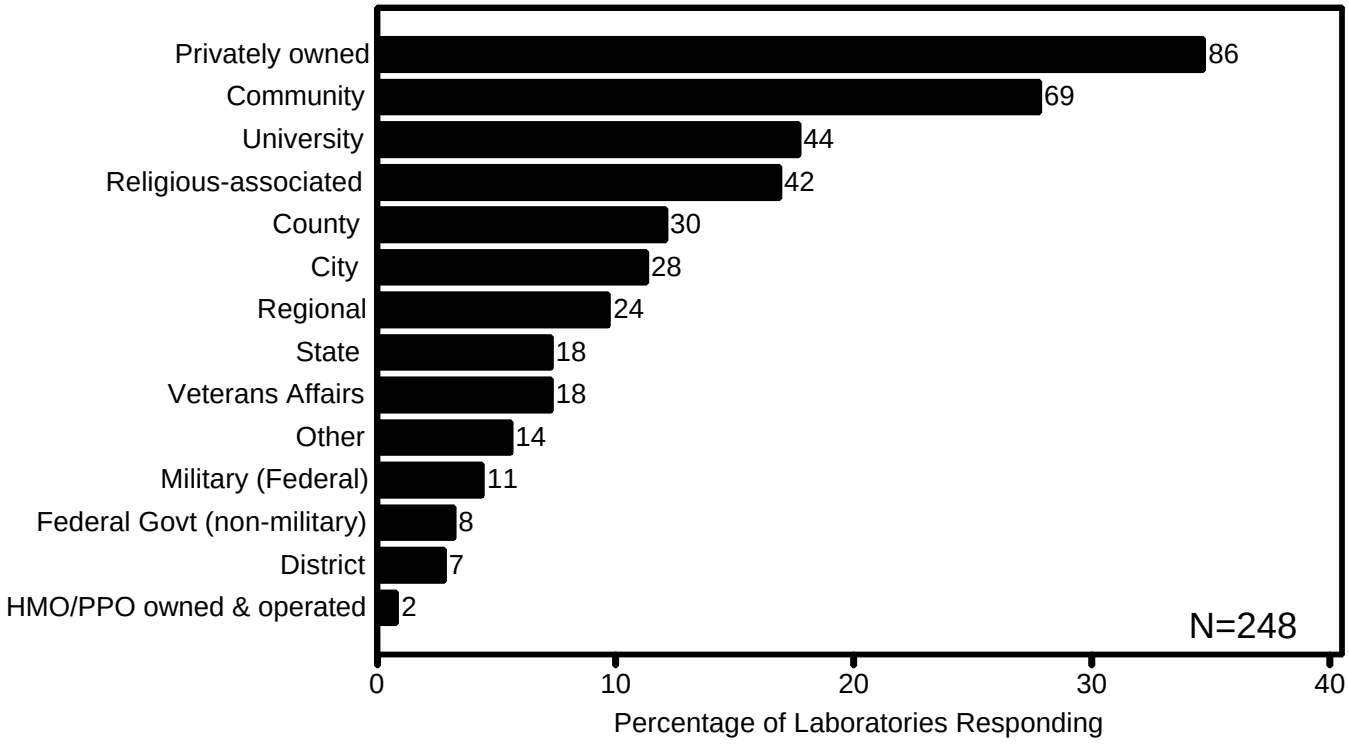
Classification of Laboratories Responding to Questionnaire Survey



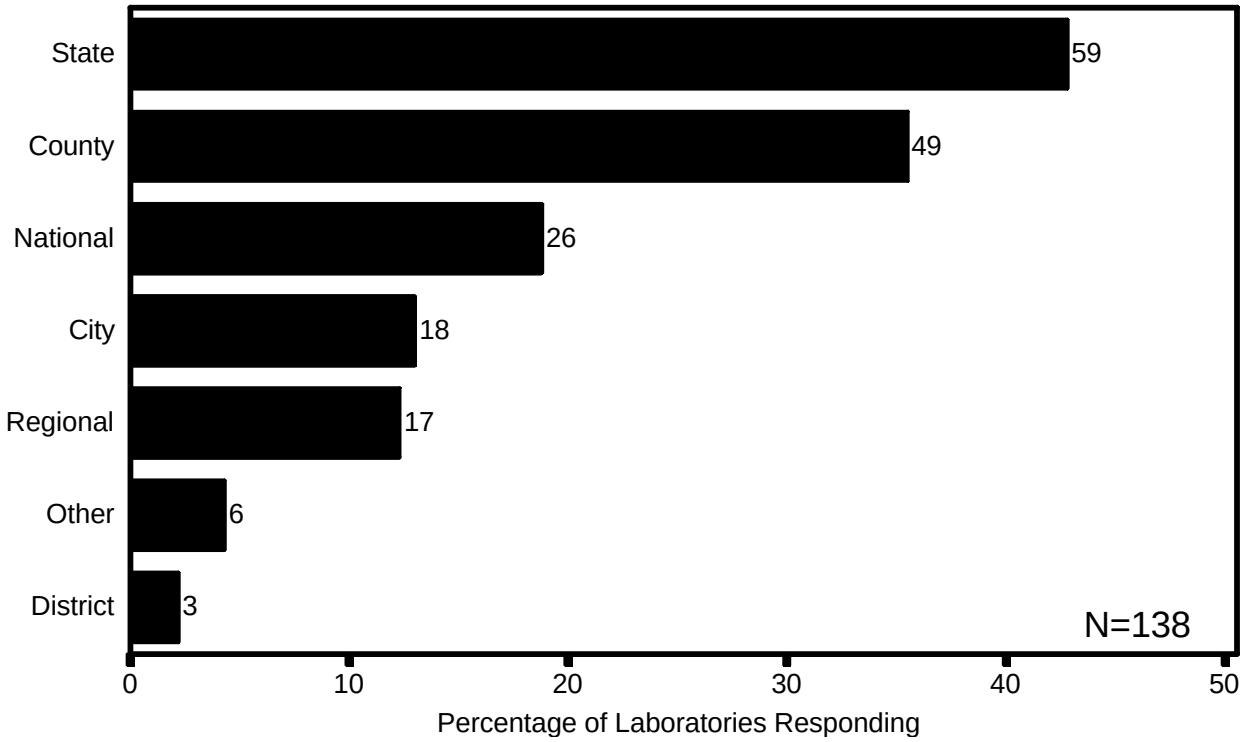
4.(a) If the laboratory type shown on your mailing label (located on page one) is BLOOD BANK, please further describe your retroviral testing laboratory (Check all that apply within your Blood Bank laboratory classification.):



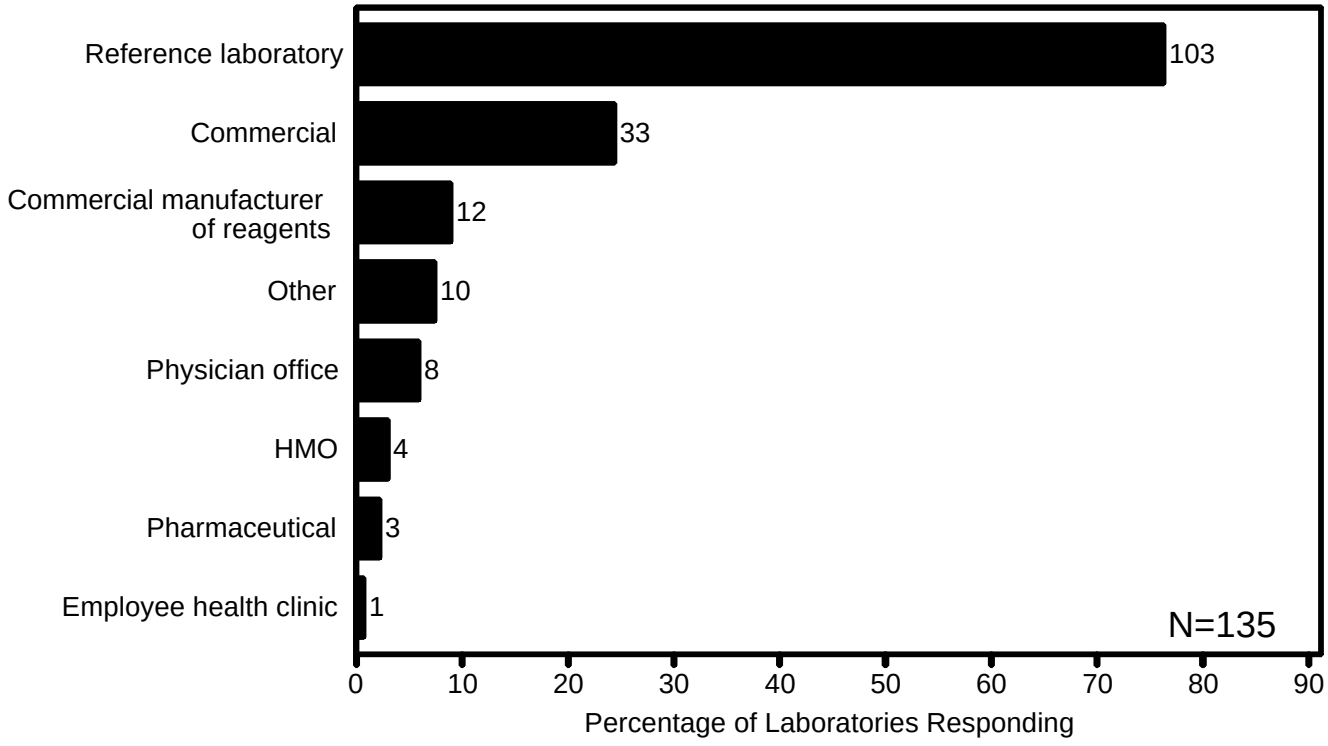
4.(b) If the laboratory type shown on your mailing label (located on page one) is HOSPITAL, please further describe your retroviral testing laboratory (Check all that apply within your Hospital laboratory classification.):



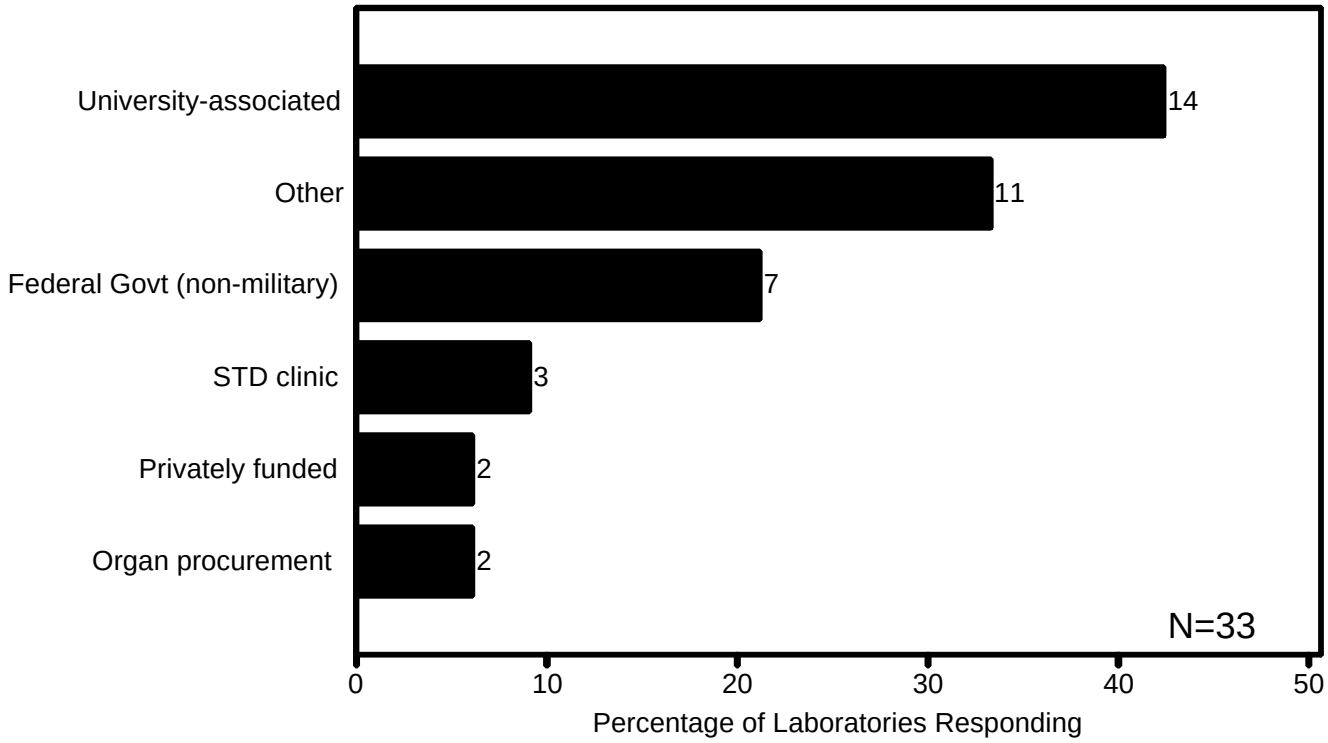
4.(c) If the laboratory type shown on your mailing label (located on page one) is HEALTH DEPARTMENT, please further describe your retroviral testing laboratory (Check all that apply within your Health Department laboratory classification.):



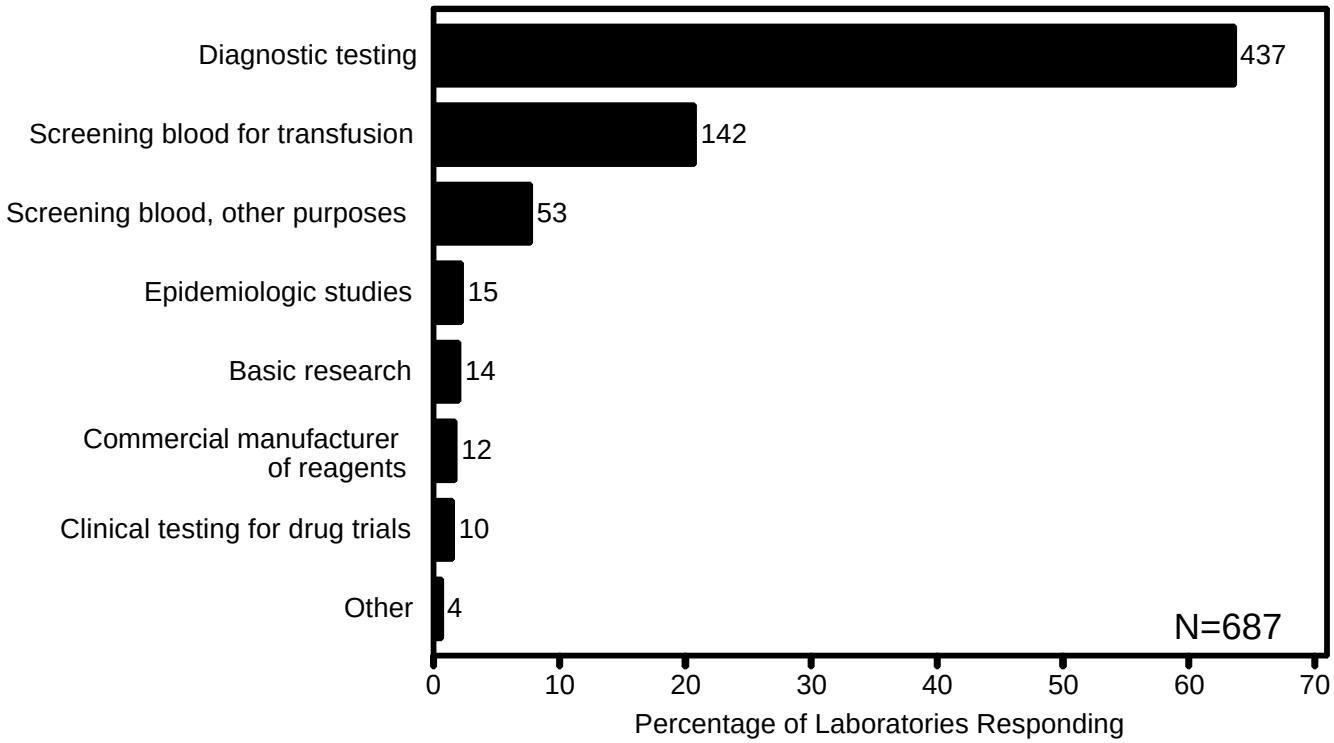
4.(d) If the laboratory type shown on your mailing label (located on page one) is INDEPENDENT, please further describe your retroviral testing laboratory (Check all that apply within your Independent laboratory classification.):



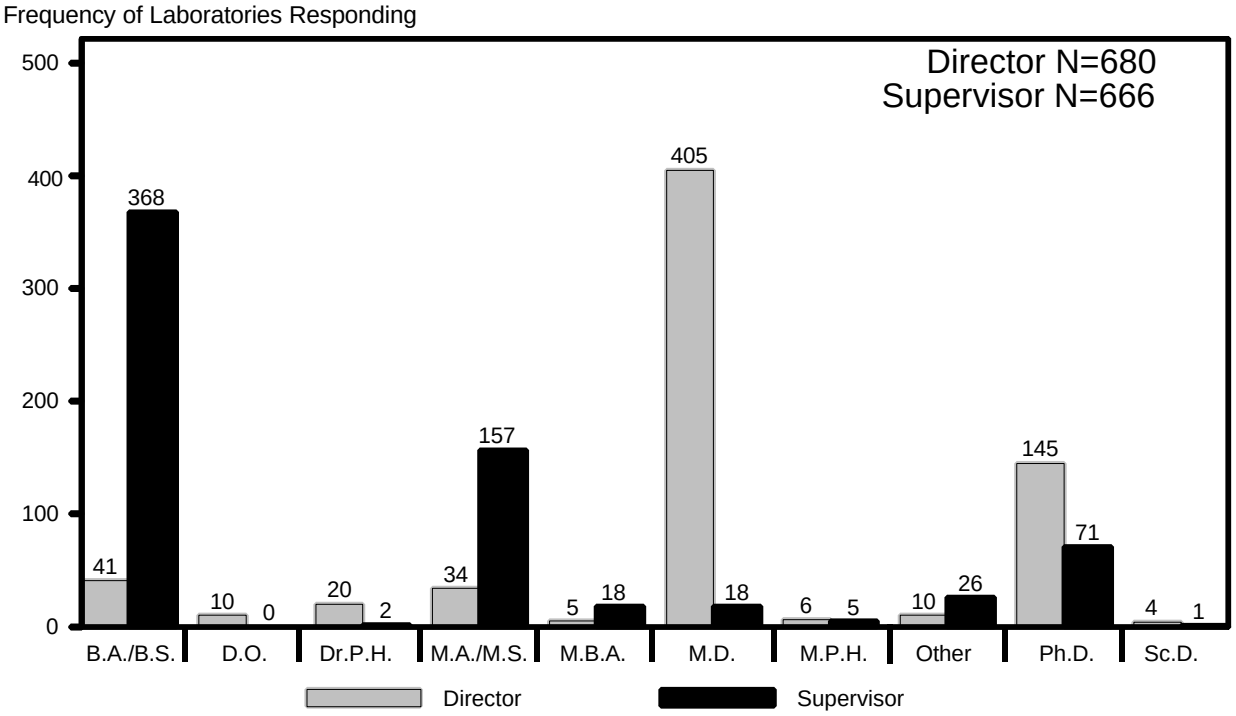
4.(e) If the laboratory type shown on your mailing label (located on page one) is OTHER, please further describe your retroviral testing laboratory (Check all that apply within your Other laboratory classification.):



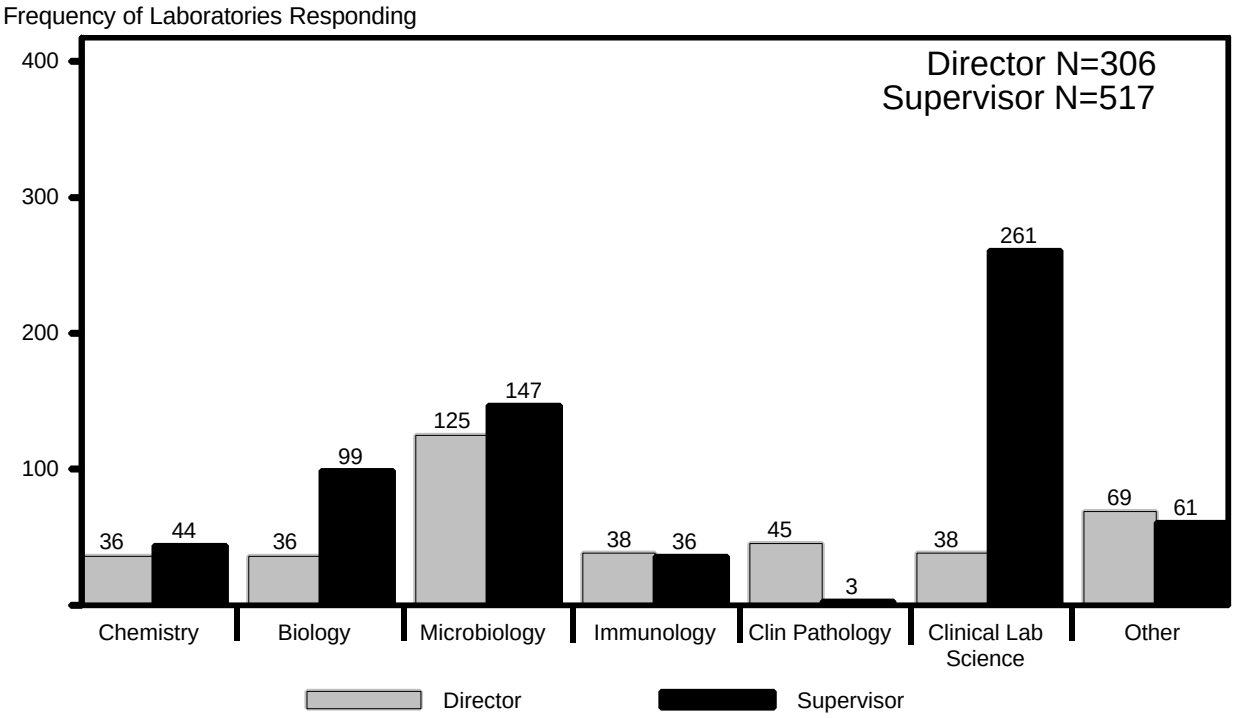
5. What is the primary purpose of your retroviral testing operation? (Choose only one.)



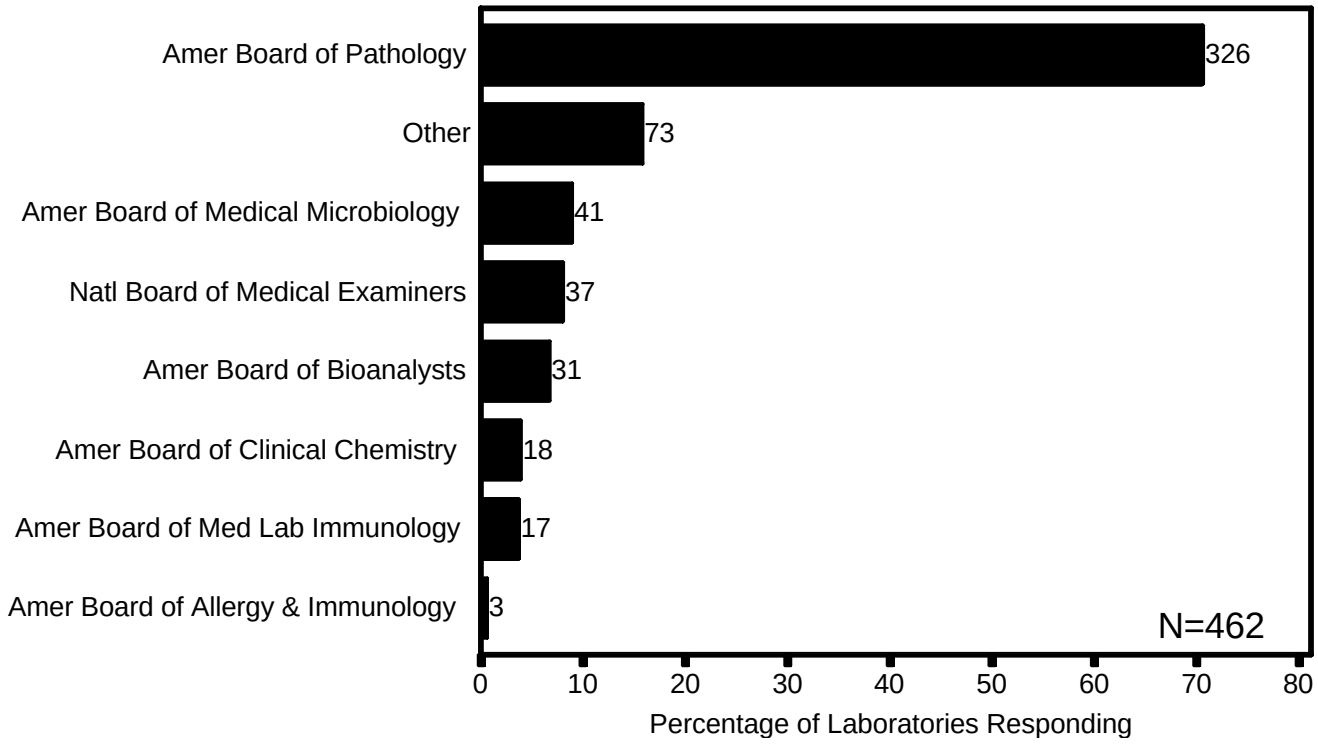
6.(a) Please choose the highest academic degree that has been awarded to your Laboratory Director and Laboratory Supervisor (Choose only one degree for each person.)



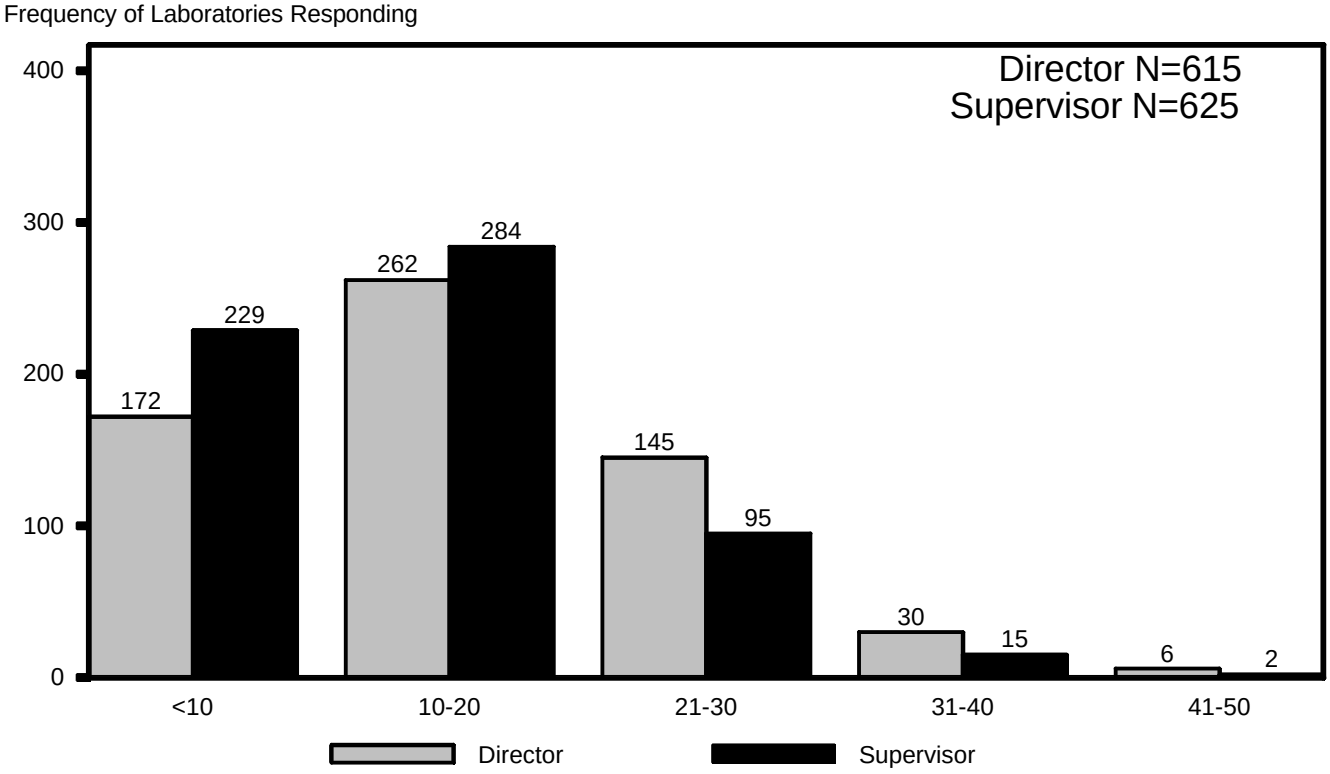
6.(b) If your Laboratory Director or Laboratory Supervisor has a degree other than M.D. or D.O., please indicate the academic discipline in which the degree was awarded (Check all that apply.):



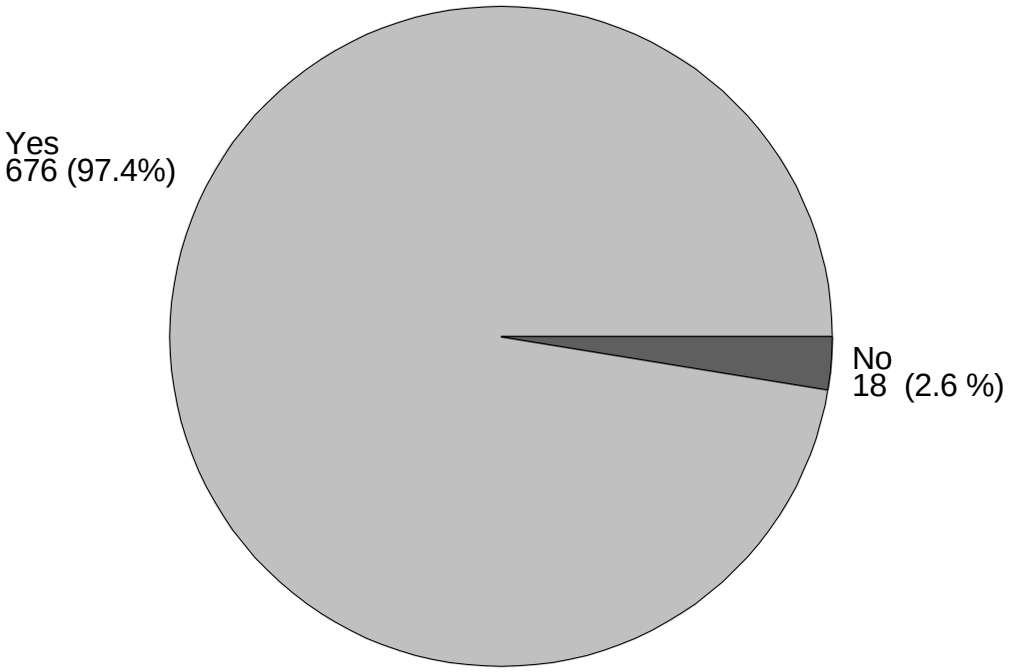
6.(c) What board certifications have been awarded to your Laboratory Director? (Check all that apply.):



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

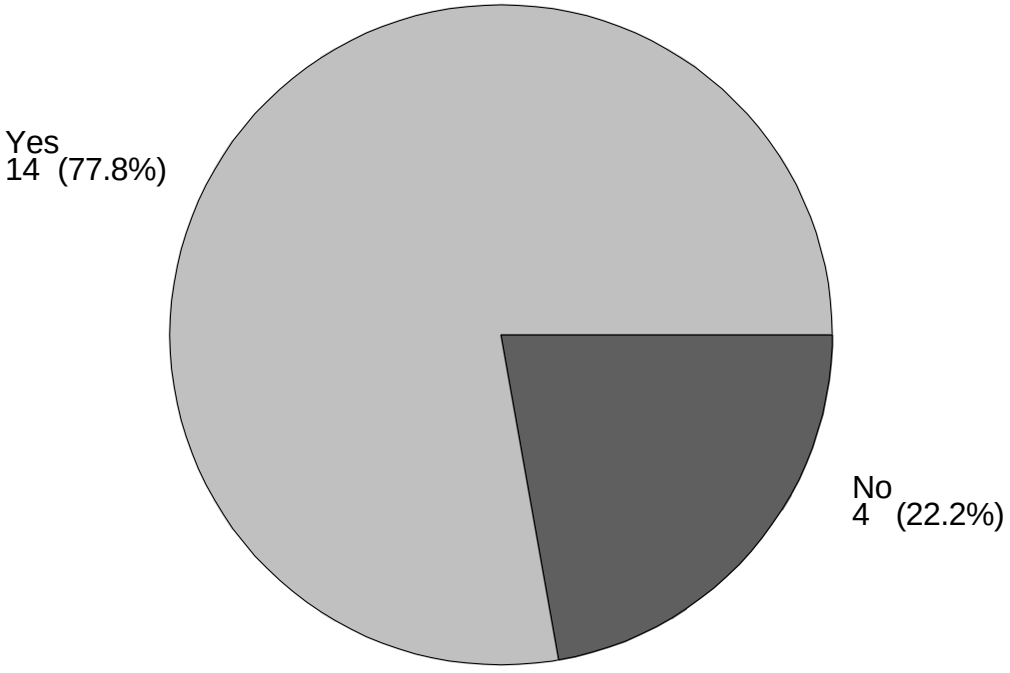


6.(e) Is your Laboratory Supervisor available to provide supervision on-site?



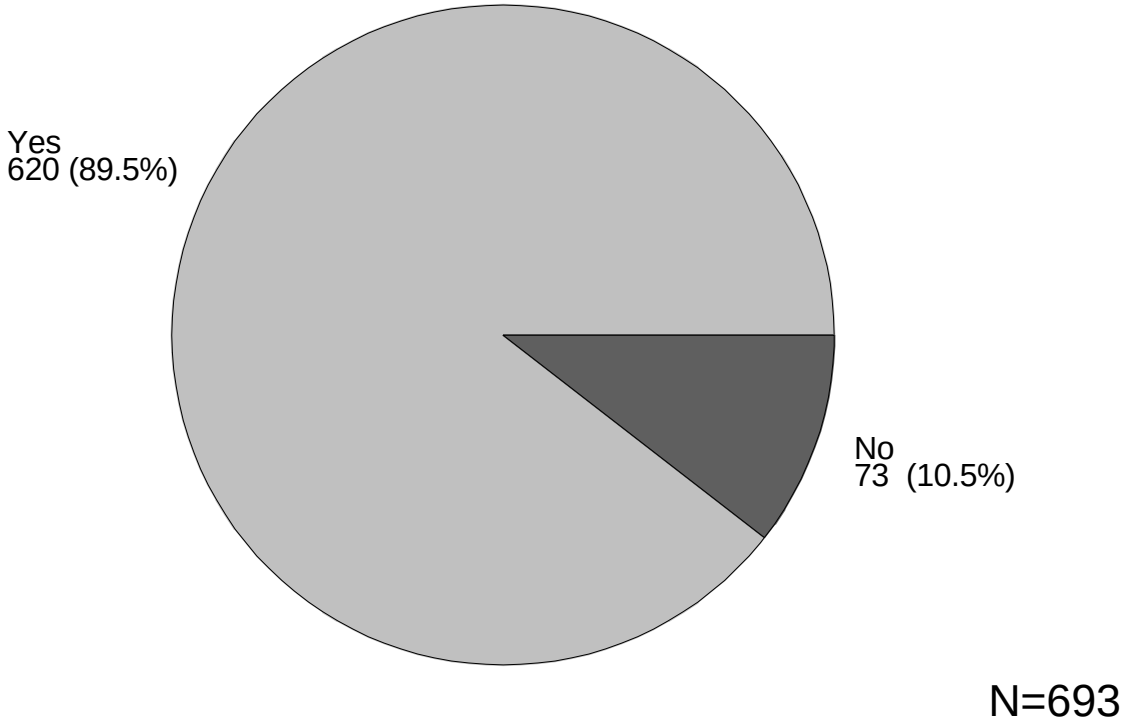
N=694

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

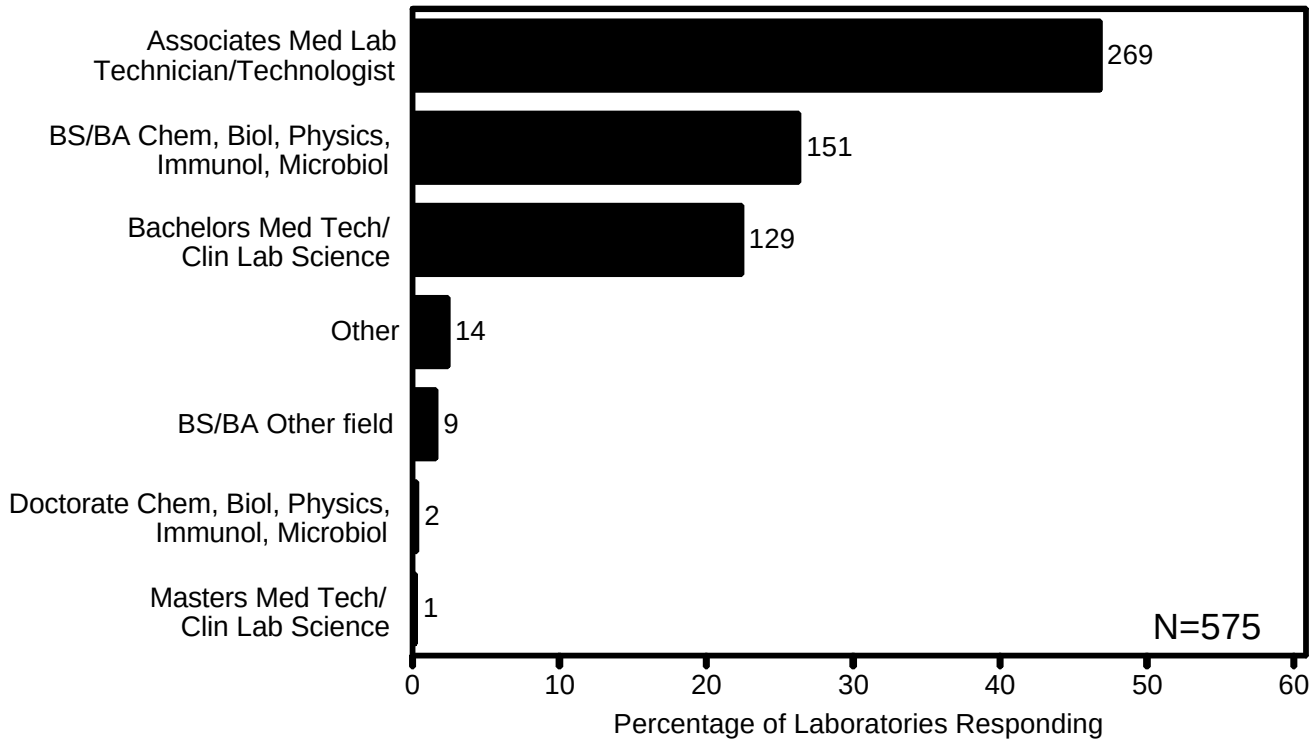


N=18

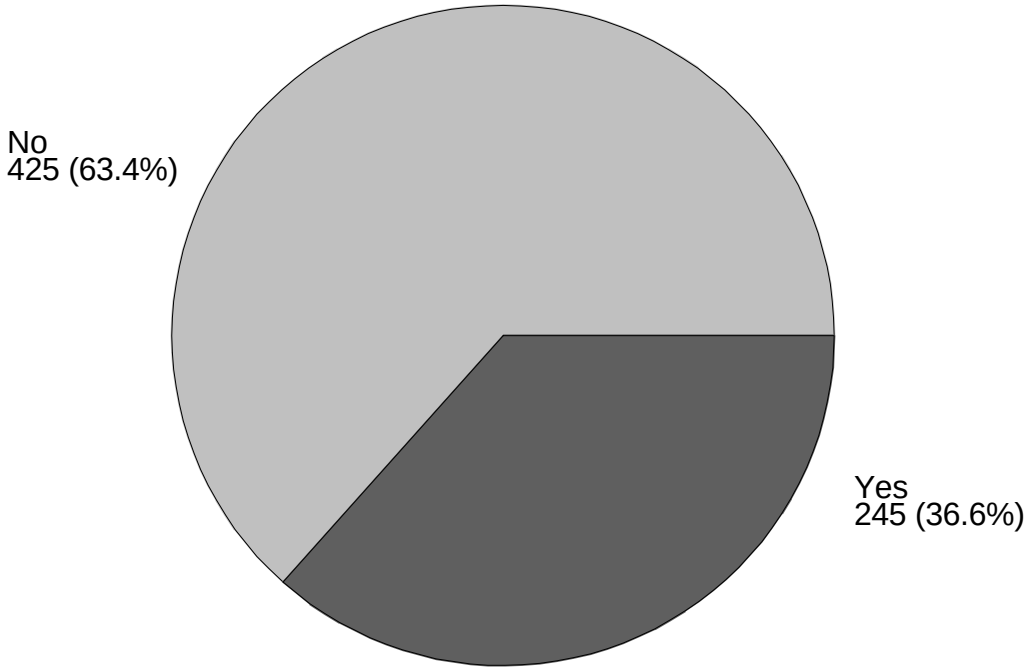
7.(a) Does your laboratory require that your retroviral testing personnel have a minimum educational degree?



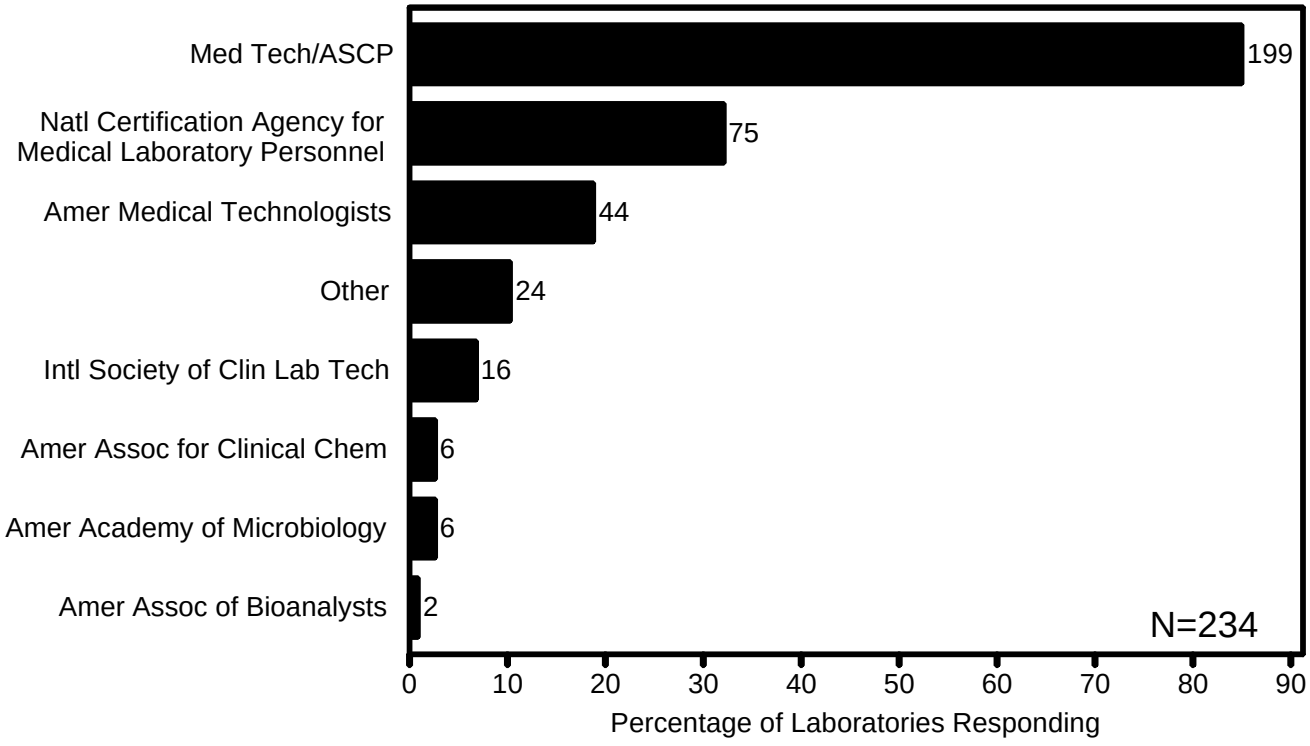
7.(b) What minimum educational degree is required of your retroviral testing personnel ? (Check only one.)



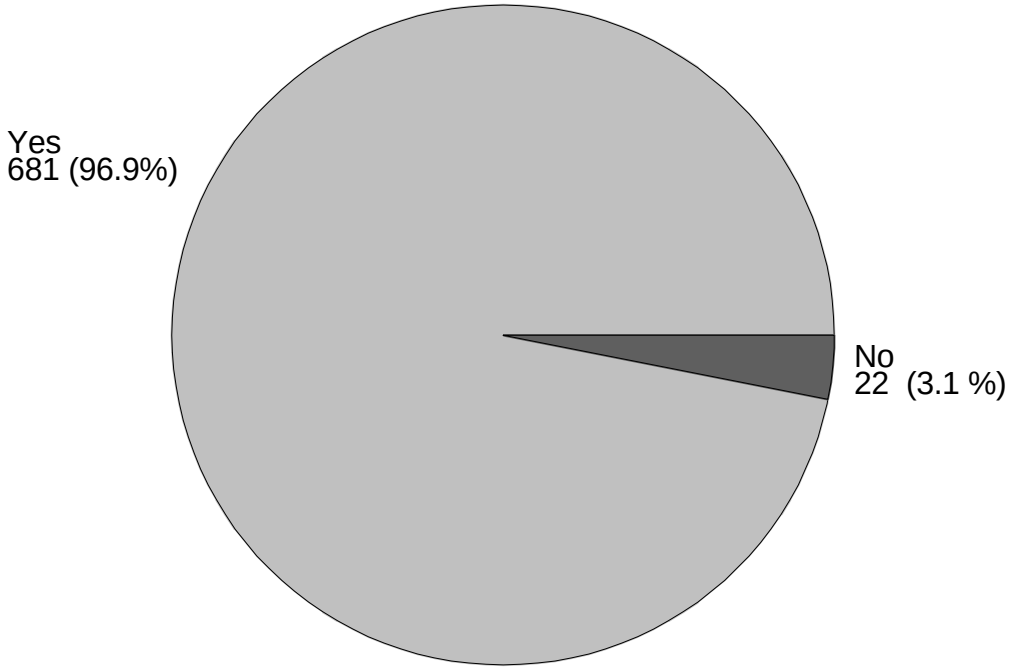
7.(c) Does your laboratory require that your retroviral testing personnel have certification by a professional organization? (Do not include certification or licensing by state, county, or foreign country.)



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

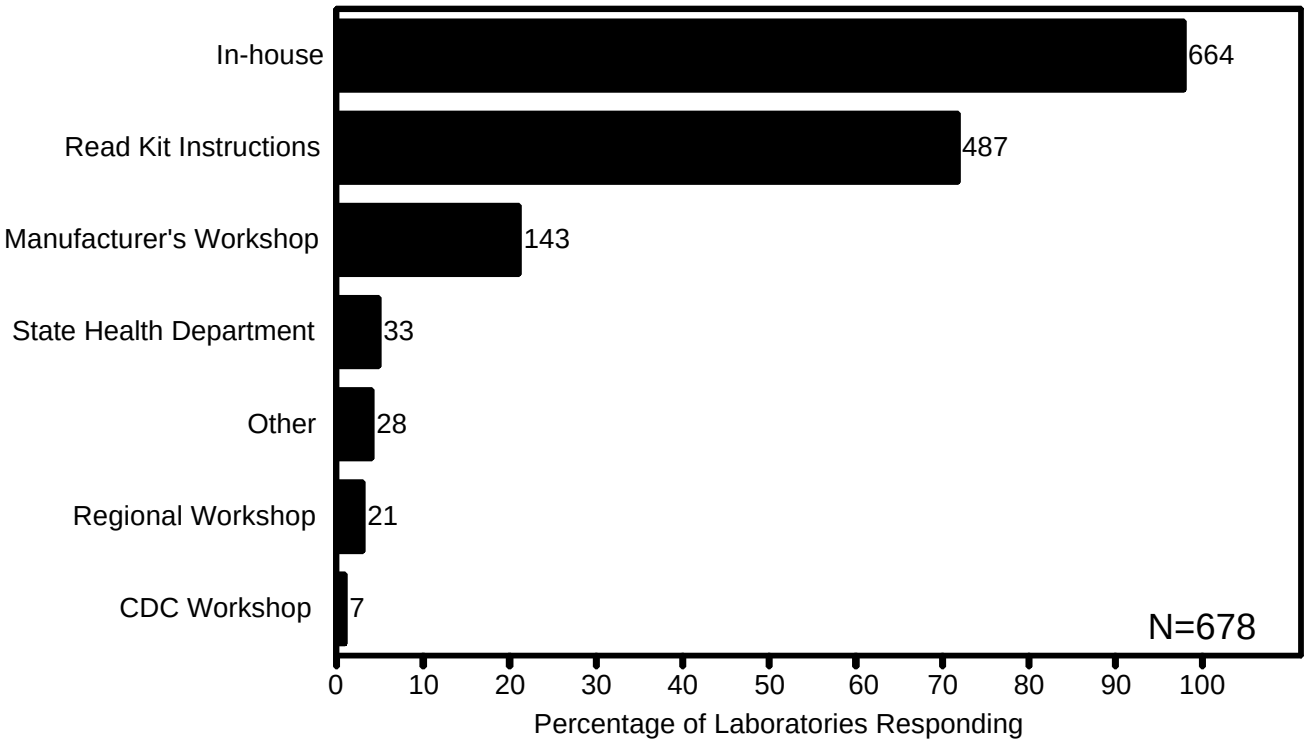


8.(a) Does your laboratory require personnel to have retroviral-specific training in testing before they are considered qualified to perform tests?

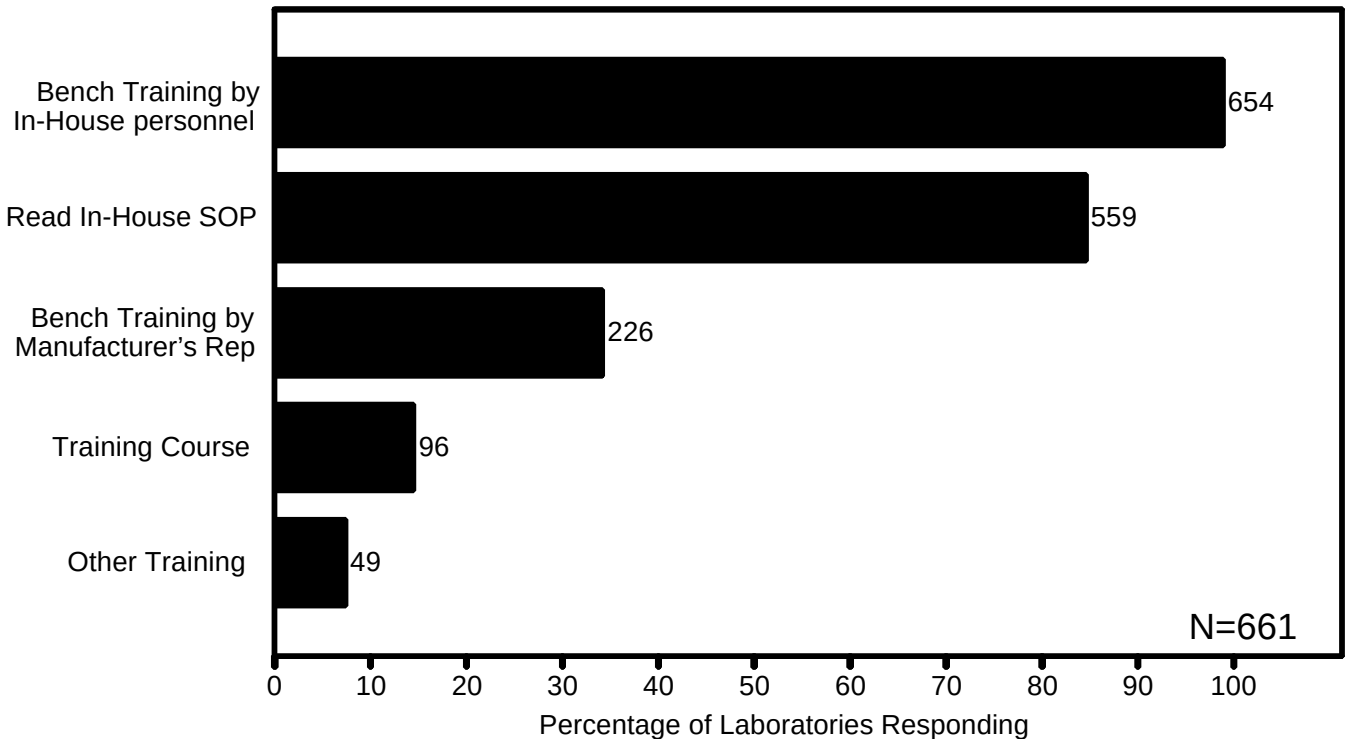


N=703

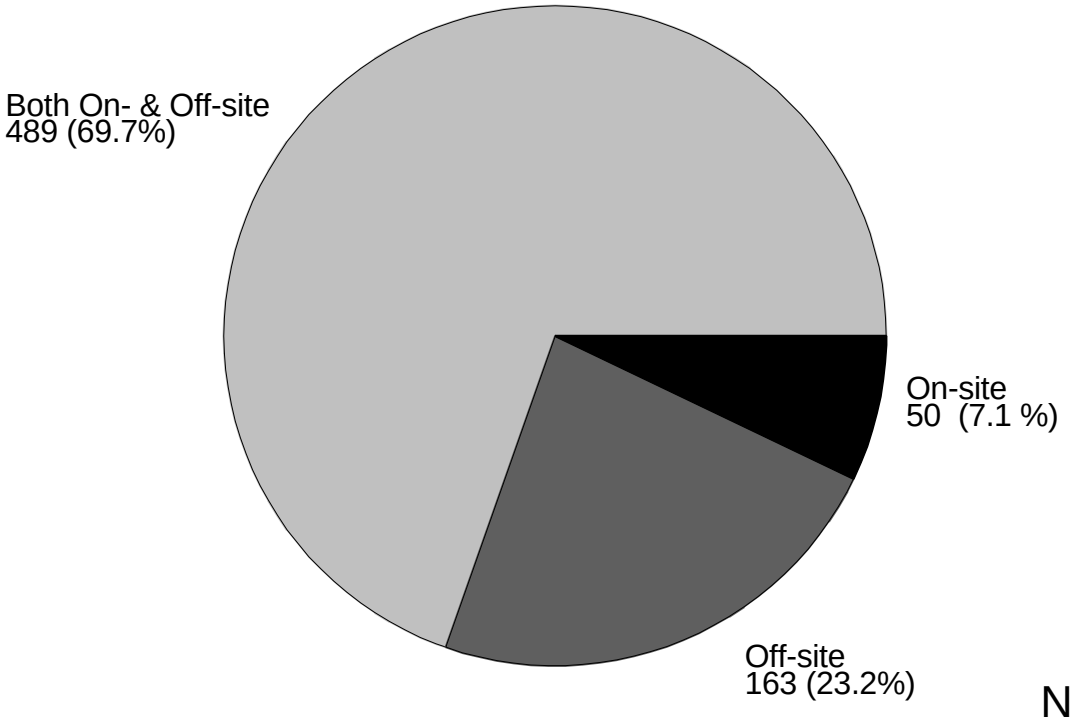
8.(b) If Yes, what training must your personnel complete before they are considered qualified to perform retroviral testing? (Check all that apply.)



8.(c) If you selected "In-house" from question 8(b), please indicate the type of in-house training (Check all that apply.):



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

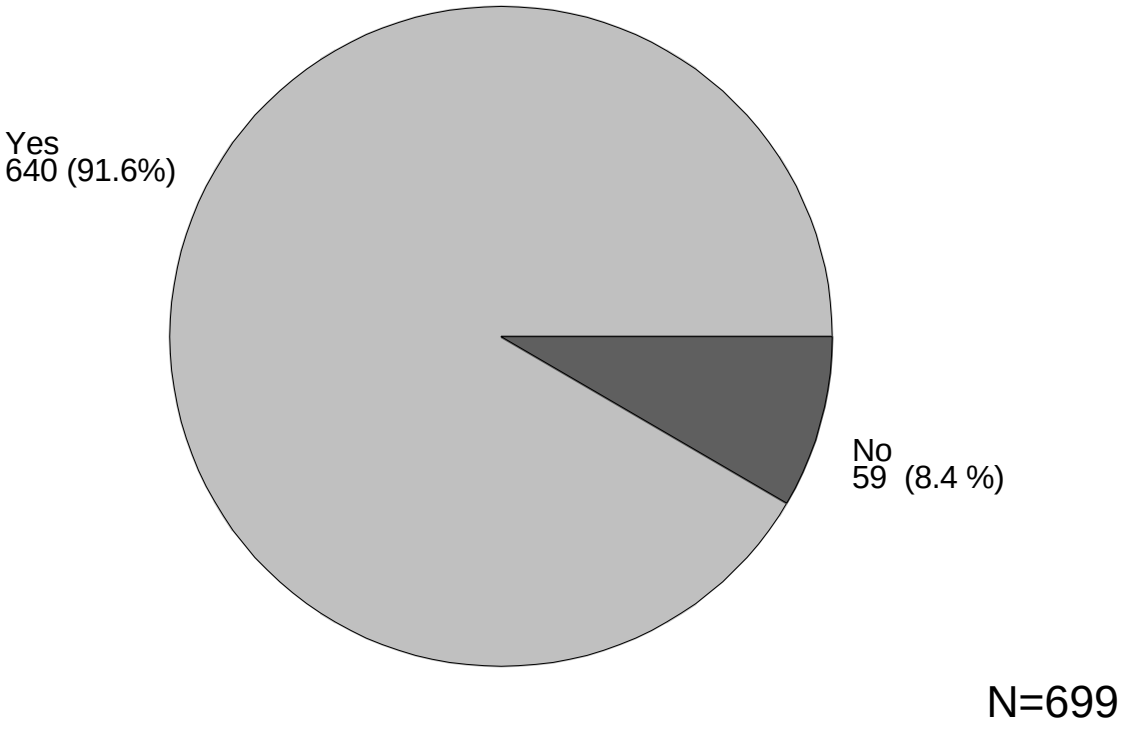


N=702

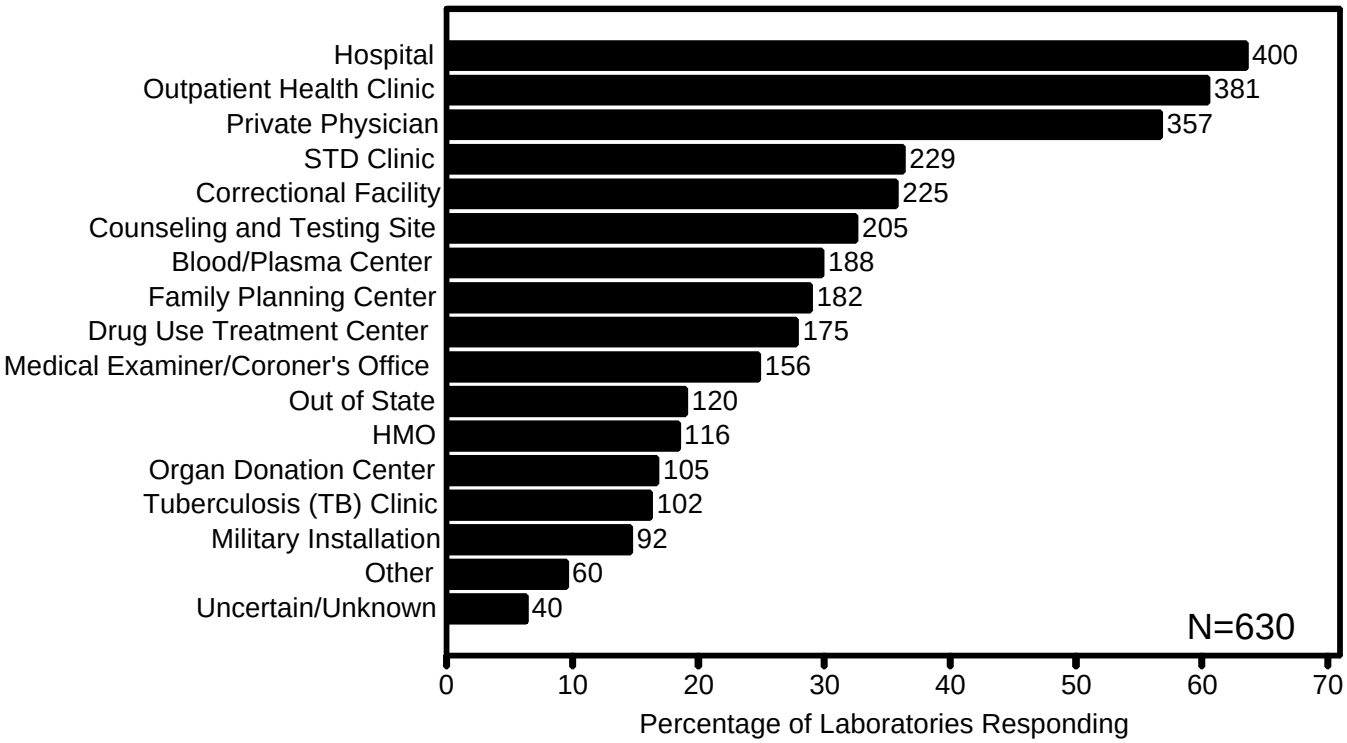
9.(b) If written instructions are provided to collection site personnel for collecting, labeling, and transporting retroviral specimens, who provides these instructions? (Check all that apply.)

Type of Instruction	Instructions NOT Provided	Testing Laboratory	Associated Institution	Person Ordering Test	Other	N =
Collecting	29 (4.4%)	561 (85.1%)	95 (14.4%)	24 (3.6%)	26 (3.9%)	659
Labeling	28 (4.3%)	563 (85.7%)	87 (13.2%)	20 (3.0%)	22 (3.3%)	657
Transporting	25 (3.8%)	560 (86.2%)	85 (13.1%)	17 (2.6%)	23 (3.5%)	650

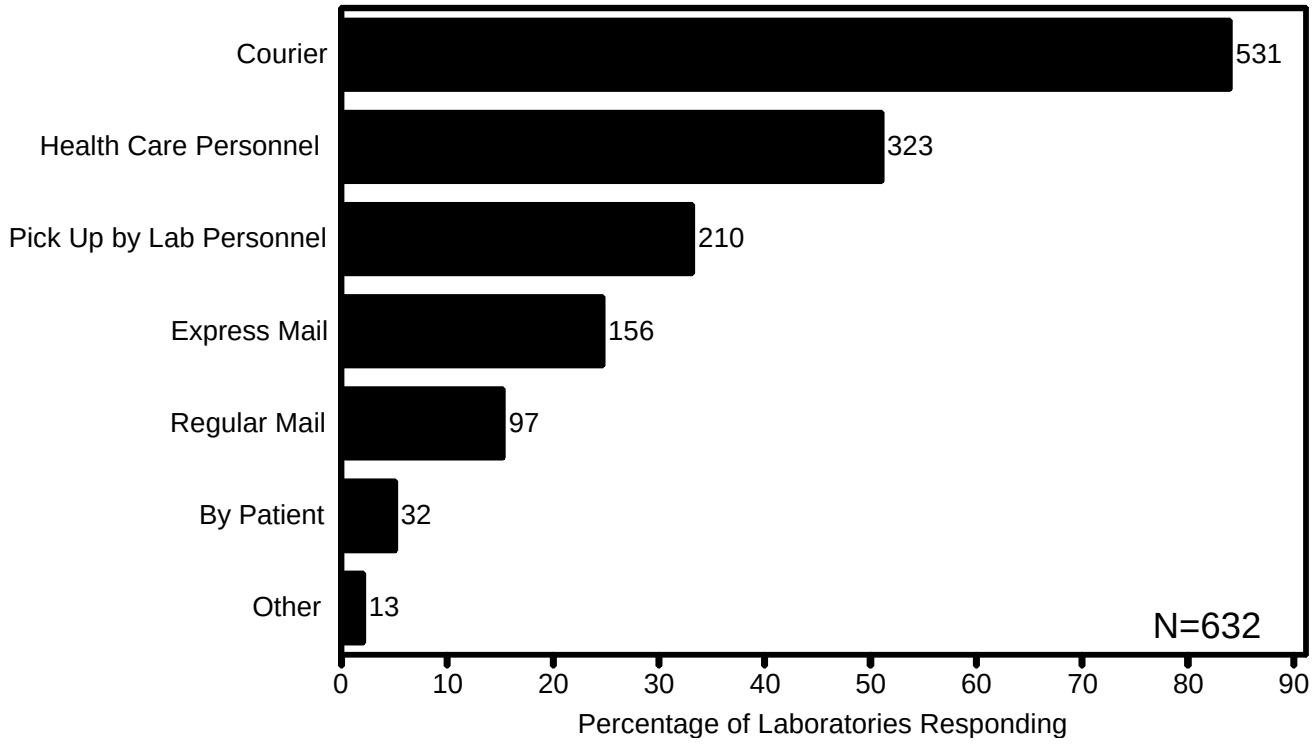
10.(a) Does your laboratory test specimens collected off-site?



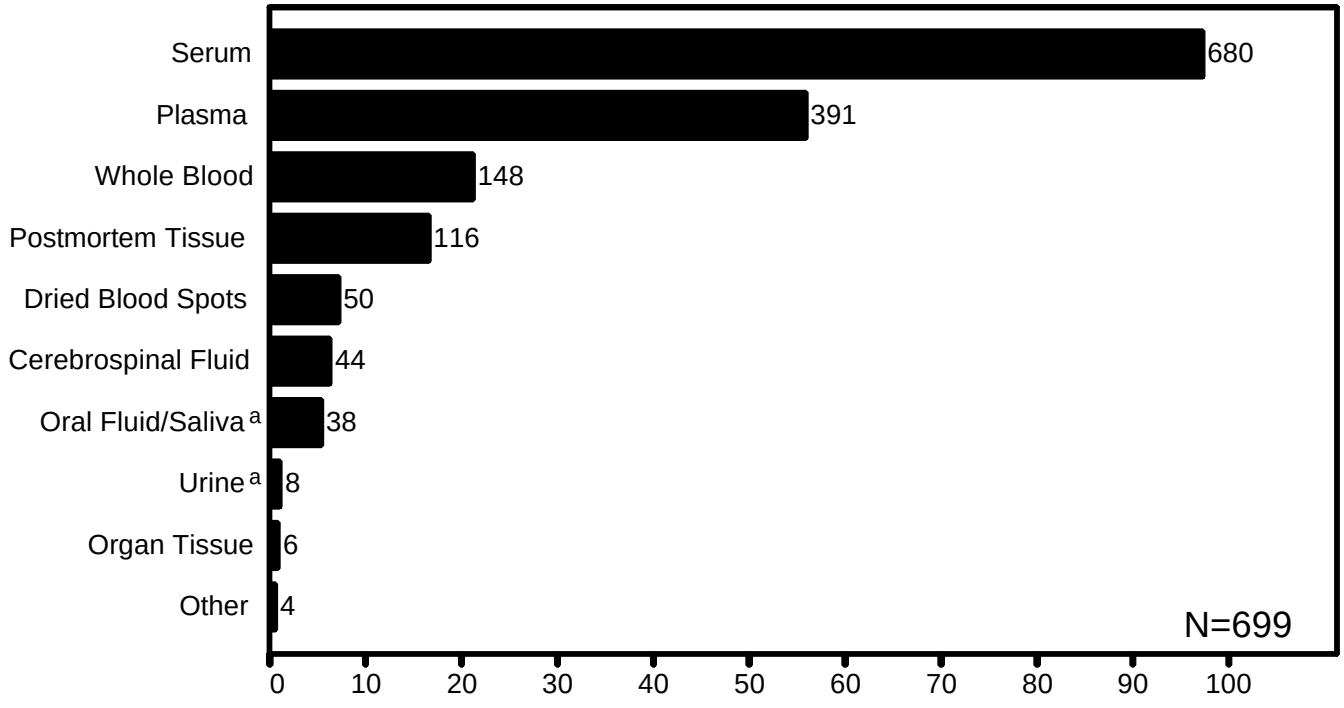
10.(b) If you test specimens collected off-site, please indicate where they are collected (Check all that apply.):



10.(c) How are the specimens collected off-site delivered to your laboratory? (Check all that apply.):



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



[a]See explanation in Introductory Comments

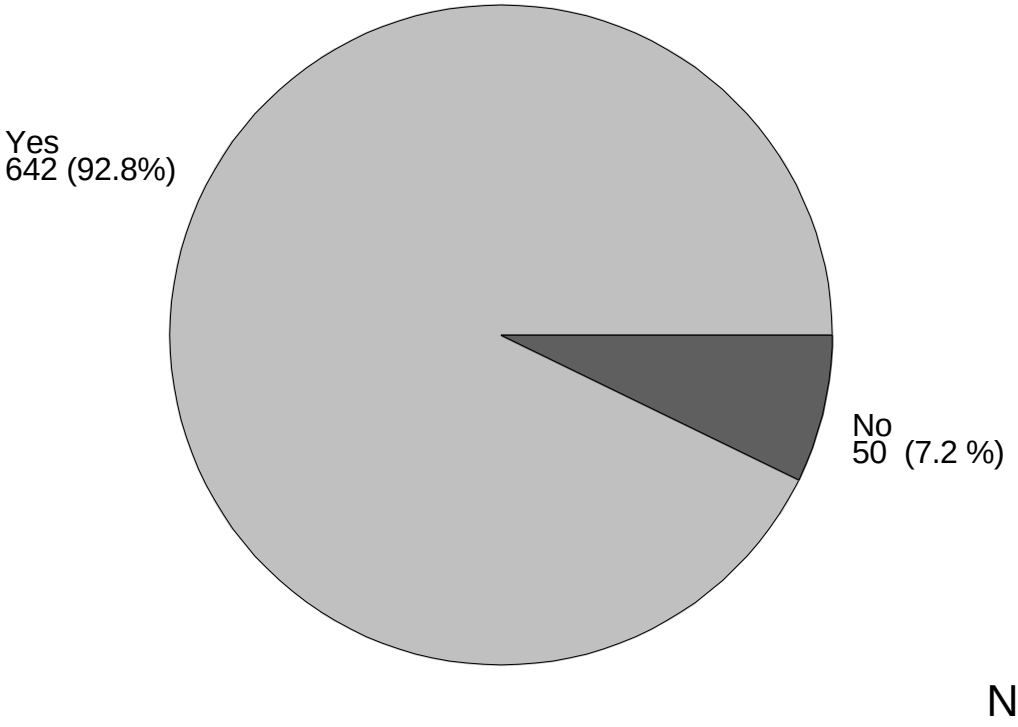
12. Please indicate which of the following procedures your laboratory routinely performs on a specimen before performing retroviral tests (Check all that apply.):

N=688

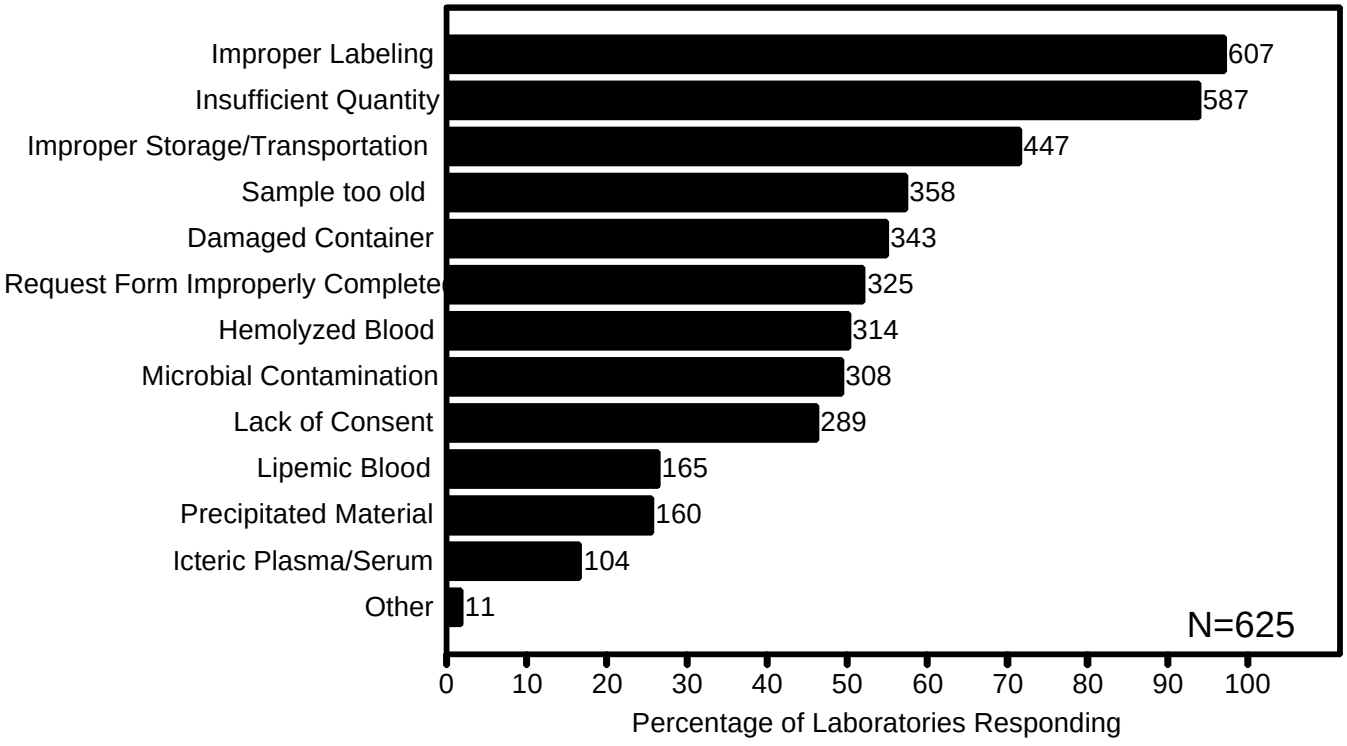
Type of Specimen	Heat Inactivation	Clarification by Centrifugation or Filtration	No Pretreatment
Whole Blood	1	152	51
Plasma	7	136	257
Serum	13	236	435
Post Mortem	0	66	41
Dried Blood Spots	2	4	34
Organ Tissue	0	6	5
Cerebrospinal Fluid	1	10	29
Oral Fluid/Saliva[a]	1	9	7
Urine[a]	0	1	3
Other	1	4	1

[a] See explanation in Introductory Comments

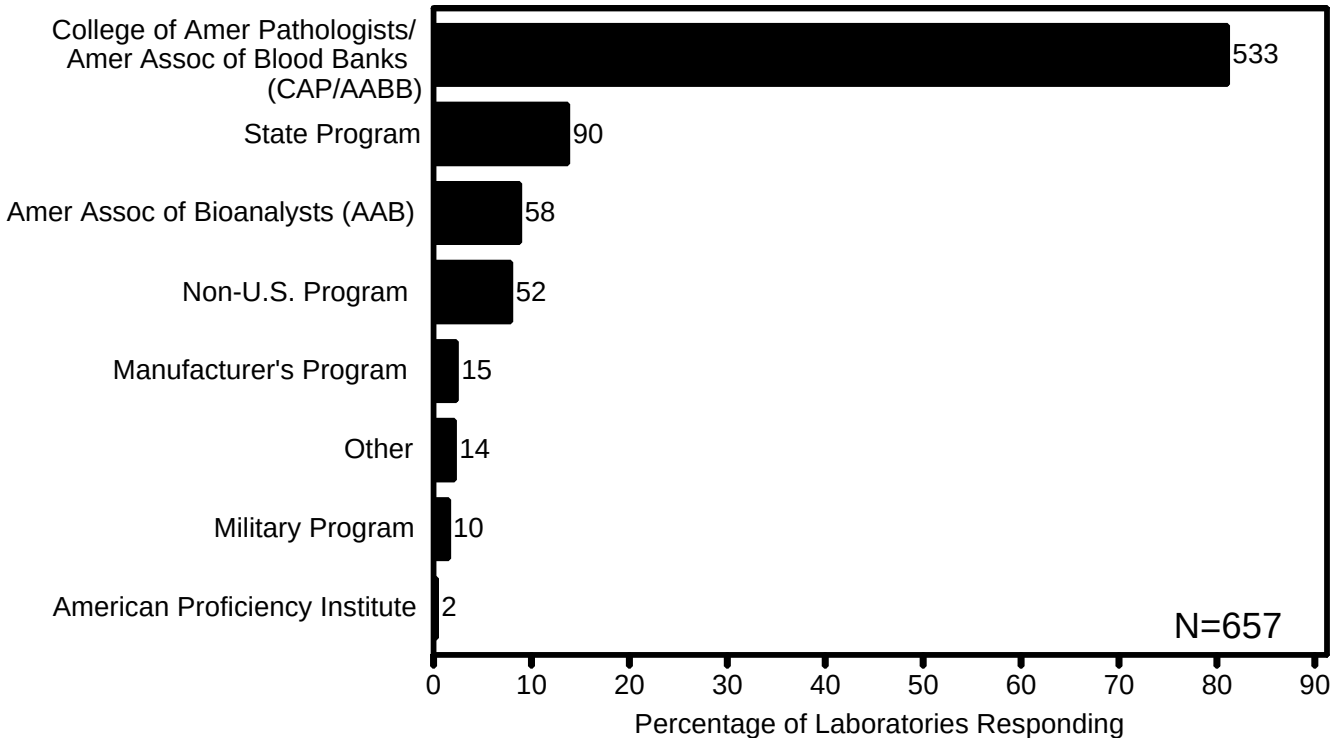
13.(a) Does your laboratory have written pre-test criteria for identifying specimens that are unsatisfactory for retroviral testing?



13.(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 all that apply.):



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



15.(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=394

	Step 1	Step 2	Step 3	Step 4	Step 5	Number of Laboratories	Percentage of Laboratories
Algorithm*	EIA-S**	EIA-D**	A			97	24.6
	EIA-S	EIA-D	WB			83	21.1
	EIA-S	EIA-D				22	5.6
	EIA-S	EIA-D	WB	A		21	5.3
	EIA-S	EIA-D	WB	O		12	3.0
	EIA-S	EIA-S	A			11	2.8
	EIA-S	EIA-D	IIF	A		7	1.8
	EIA-D	WB				7	1.8
	EIA-S	EIA-D	WB	IIF	A	6	1.5
	EIA-S	A				5	1.3
	EIA-S	EIA-D	IIF			4	1.0
	EIA-S	EIA-D	WB/A			4	1.0
	EIA-S	EIA-D/A				4	1.0
Other Algorithms						111	28.2

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 97 unique algorithms were reported

** EIA data in this table includes both manual and non-manual procedures

15.(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=399

	Step 1	Step 2	Step 3	Step 4	Number of Laboratories	Percentage of Laboratories
Algorithm*	EIA 1/2-S**	EIA 1/2-D**	A		143	35.8
	EIA 1/2-S	EIA 1/2-D			31	7.8
	EIA 1/2-S	EIA 1/2-D	WB-1		29	7.3
	EIA 1/2-S	EIA 1/2-D	WB-1	A	12	3.0
	EIA 1/2-S	EIA 1/2-D	WB-1/A		5	1.3
	EIA 1/2-S	EIA 1/2-S	A		5	1.3
	EIA 1/2-S	EIA 1/2-D	WB-1/WB-2		4	1.0
	EIA 1/2-S	EIA 1/2-D/A			4	1.0
	EIA 1/2-S	EIA 1/2-S	WB-1		4	1.0
Other Algorithms					162	40.6

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 142 unique algorithms were reported

** EIA data in this table includes both manual and non-manual procedures

16. 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=631

Number of Years	EIA	WB	IIF	PCR	PA	HIV-1 Antigen	Viral Culture	Other
1-3	24	13	11	90	0	124	4	36
4-6	76	40	10	12	4	28	6	16
7-9	98	54	12	0	5	31	9	7
10-12	362	114	20	0	4	25	10	3
13-15	40	10	2	0	1	0	4	1
>15	9	4	1	0	0	0	0	0

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

N=663

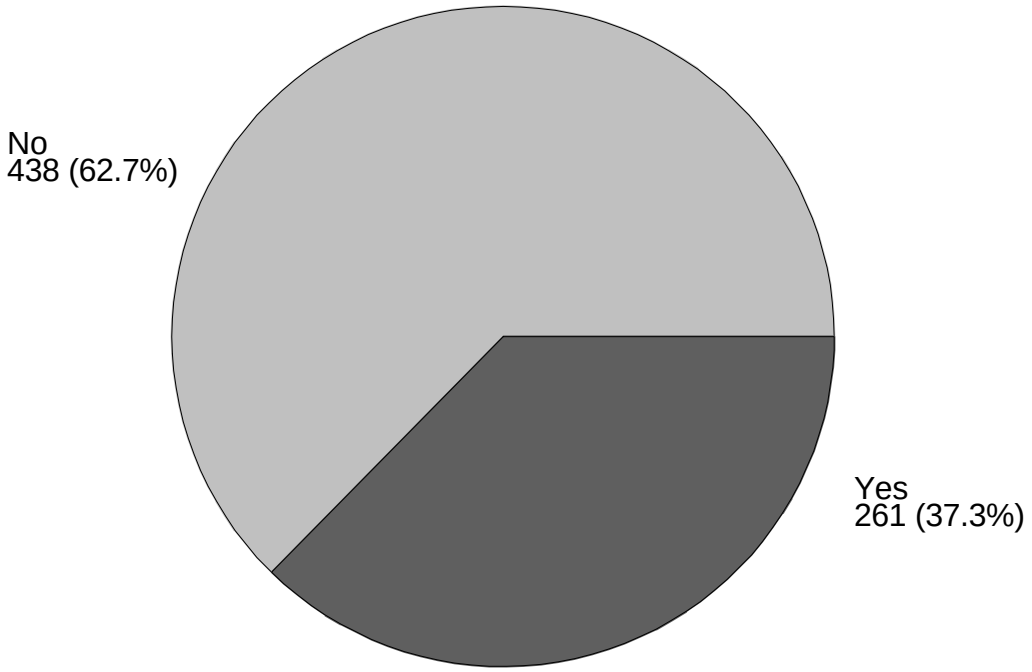
Number of Employees	EIA	WB	IIF	PCR	PA	HIV-1 Antigen	Viral Culture	Other
1-2	60	55	15	49	1	39	10	17
3-4	187	84	20	40	4	53	14	19
5-6	162	57	12	12	3	42	7	10
7-8	79	20	5	1	2	28	0	5
9-10	61	11	1	0	2	20	1	4
>10	89	15	1	2	1	22	1	4

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

N=701

Type of procedure	EIA	WB	IIF	Other
No written procedures	2	0	0	3
In-house written protocol	542	191	38	62
Manufacturer's insert	609	226	46	68
Provided by the State Health	27	7	2	2
Other sources	23	17	2	8

18.(a) Does your laboratory perform HIV Western blot testing?



N=699

18.(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

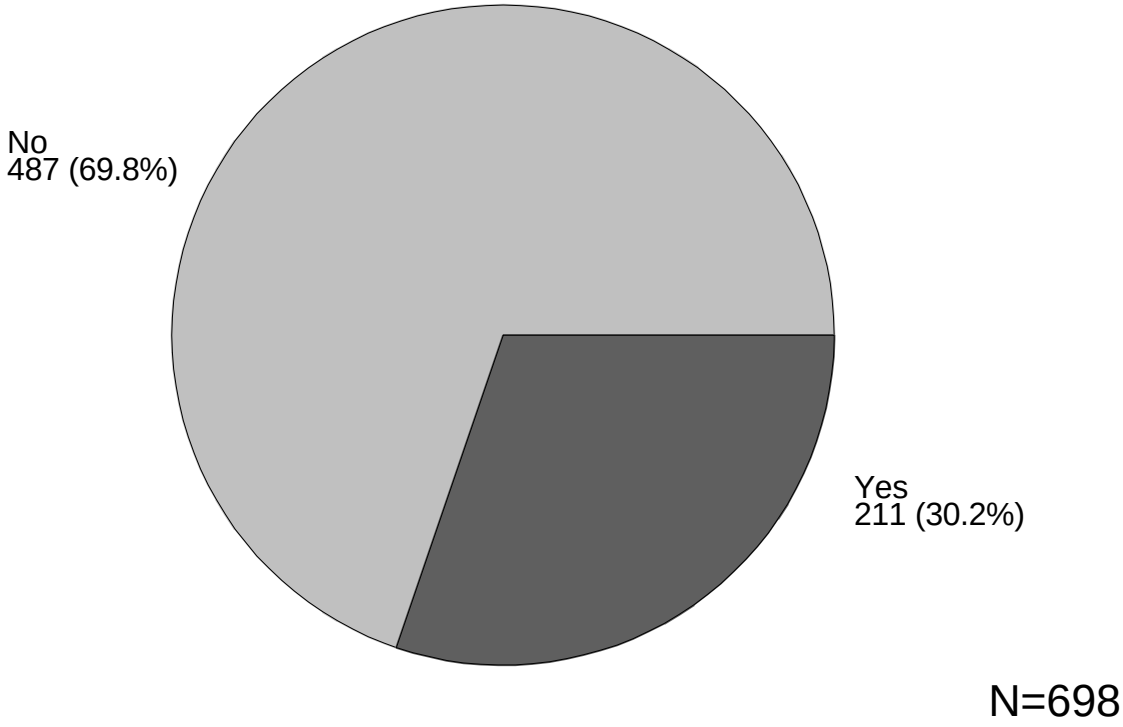
Band Patterns	Number of Laboratories	Percentage of Laboratories
Any two of p24, gp41, gp120/gp160	212	81.9
Other	19	7.3
Two env bands w/ or w/o gag or pol bands	13	5.0
One protein from each: gag (p17/18, p24, p55), and env (gp41, gp120, gp160), and pol (p31, p51, p65/66)	8	3.1
p24 or p31, and gp41 or gp120/gp160	5	1.9
p24 plus p31, and either gp41 or gp120/gp160	2	0.8

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

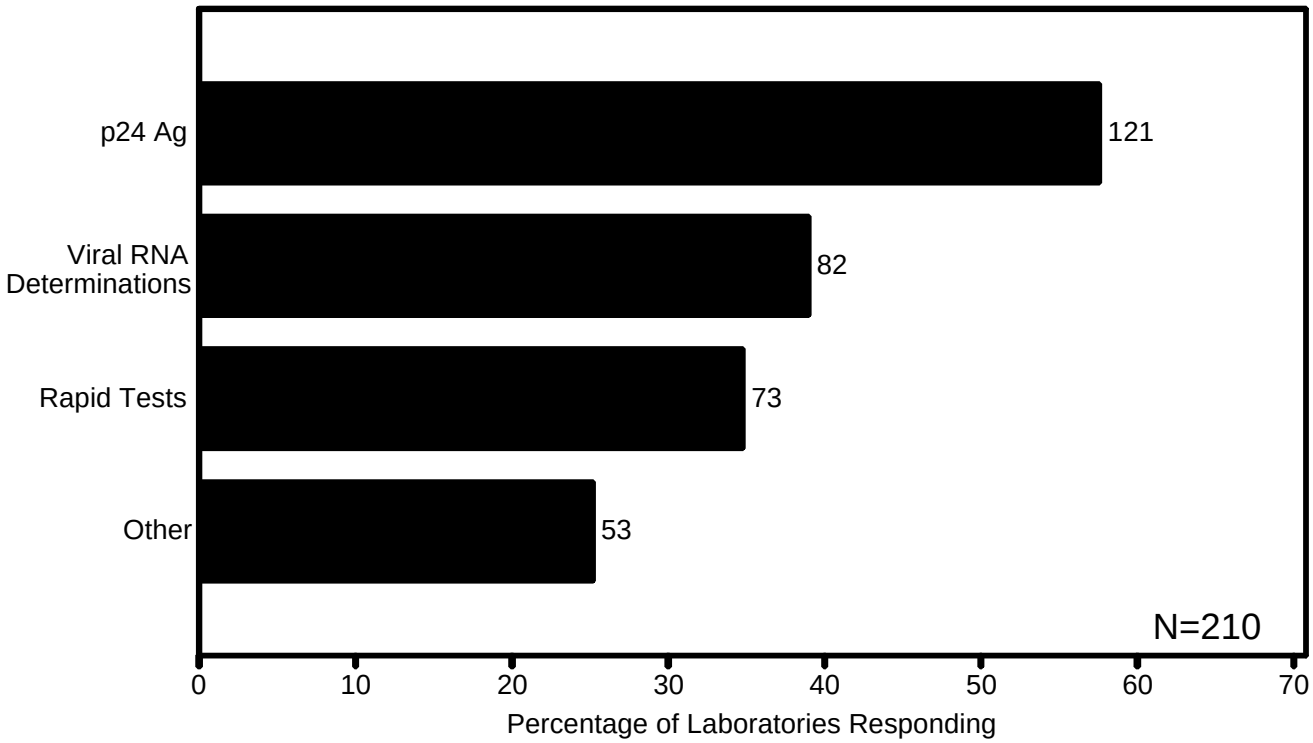
N=260

Band Patterns	Number of Laboratories	Percentage of Laboratories
No bands present	187	71.9
No HIV-1 specific protein band(s) (i.e., 17/18, 24, 31, 41, 51, 55, 65/66, 120, 106)	64	24.6
Other	9	3.5

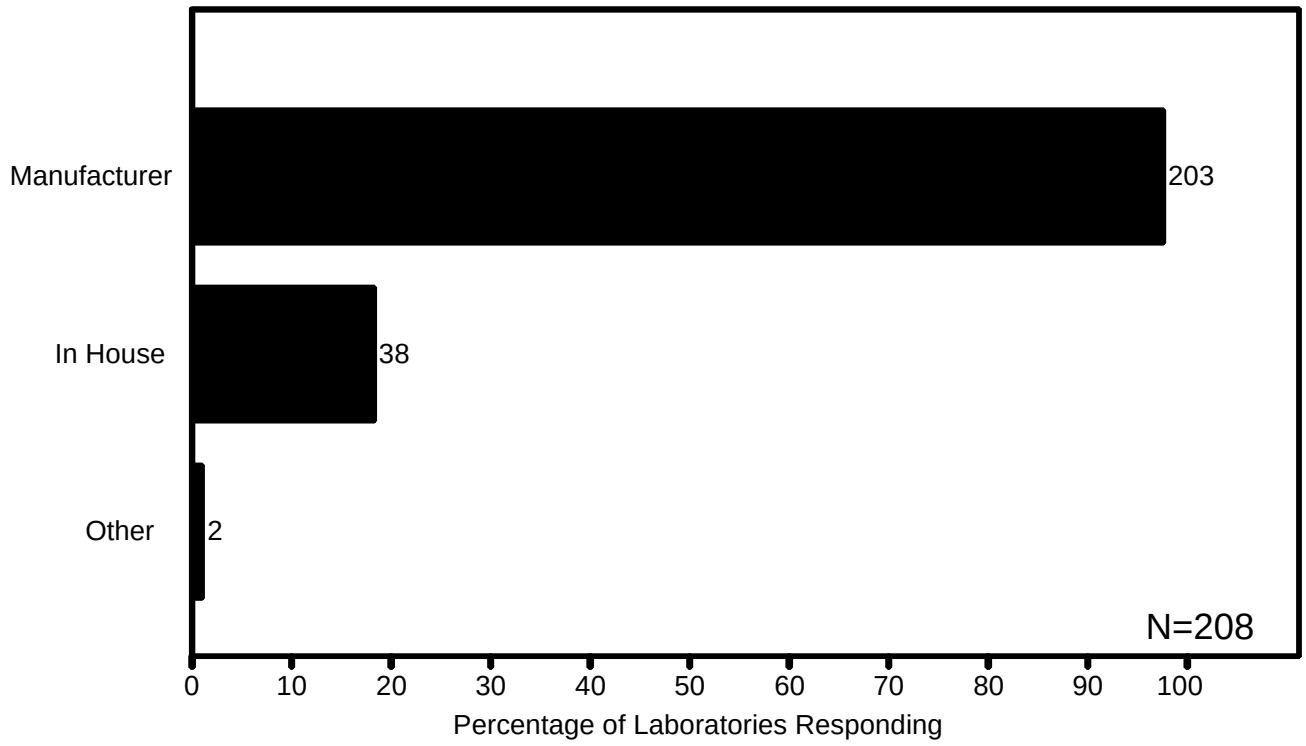
19.(a) Do you perform an HIV test other than EIA, WB, or IIF to detect HIV-1 infection?



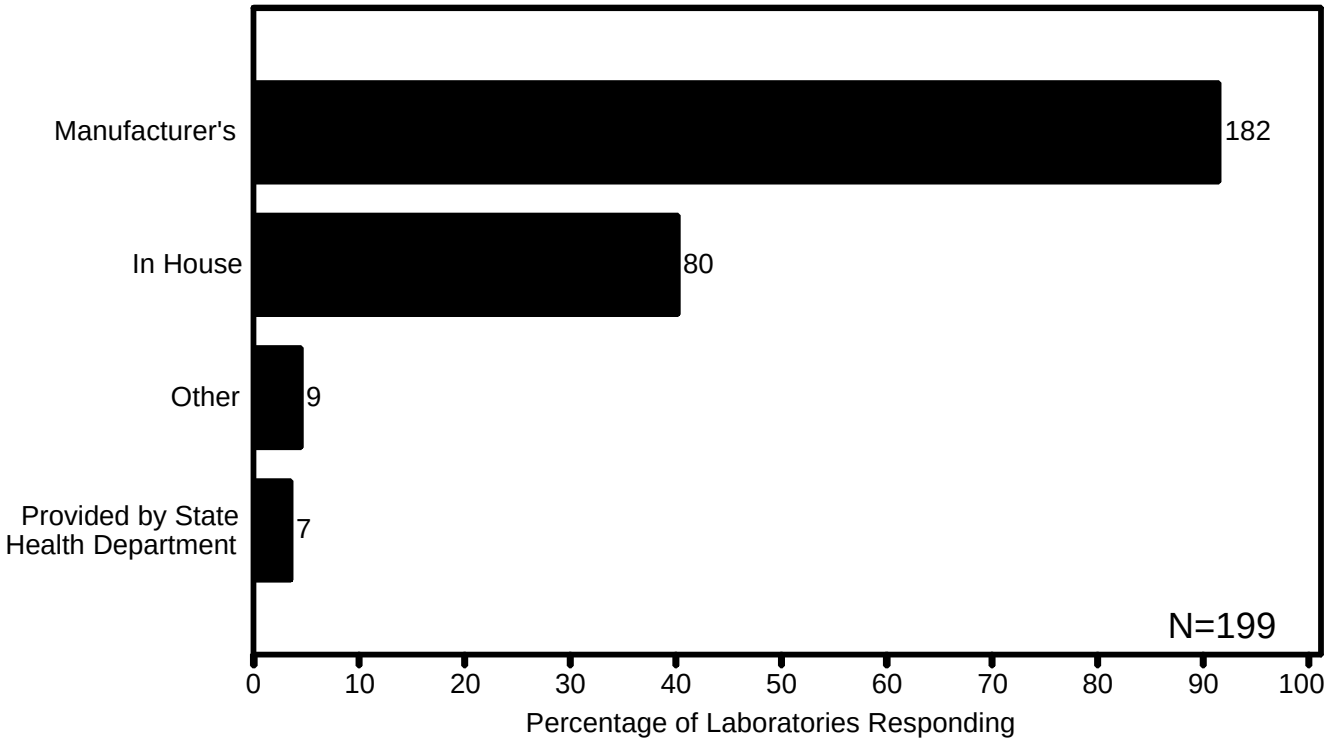
19.(b) If yes, indicate below the other tests performed in your laboratory (Check all that apply.):



19.(c) Source of reagents (Check all that apply.):



19.(d) What procedure does your laboratory follow for performing HIV tests other than EIA, WB, or IIF? (Check all that apply.)



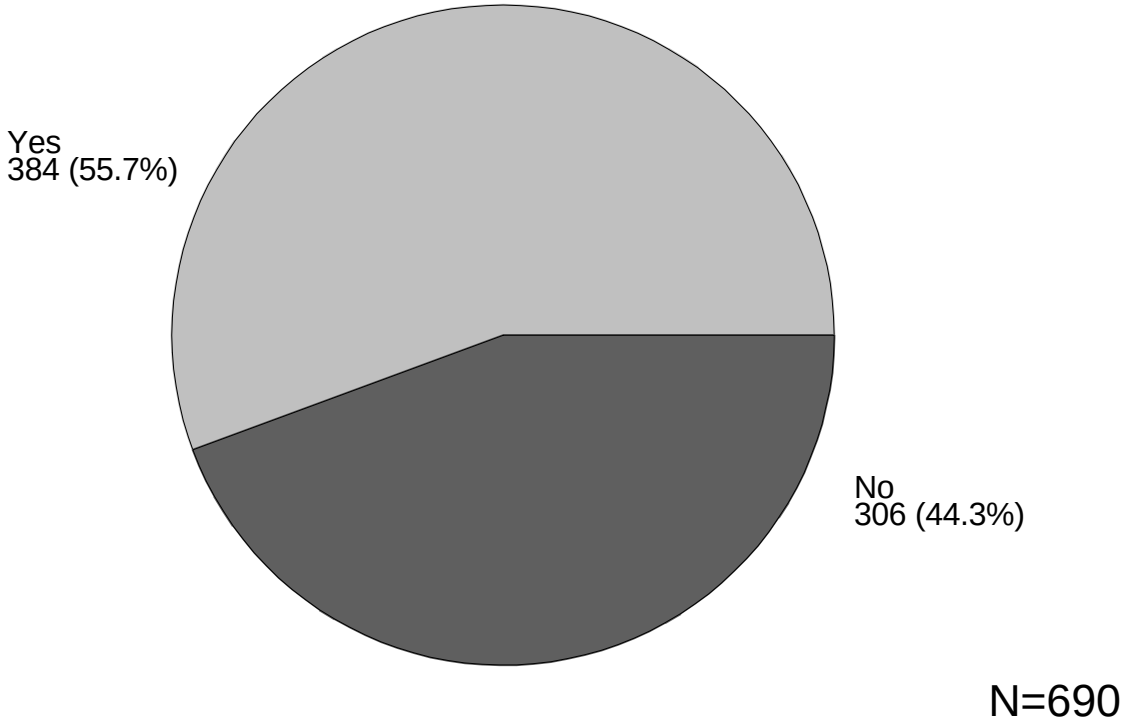
20. Please indicate the frequency with which your laboratory uses HIV control sera/plasma (other than kit manufacturer controls) for each of the test methods below (Check <u>all</u> that apply.):

N=496

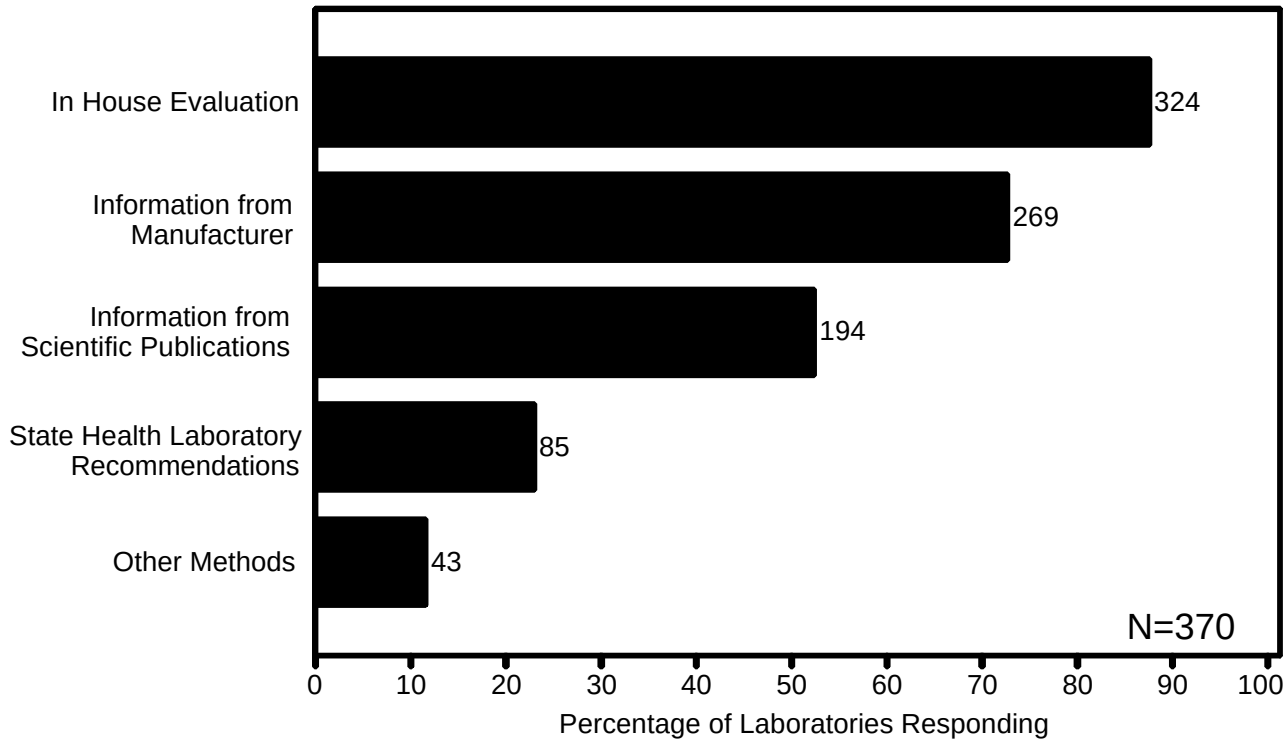
Test Method	Each Test[a]	Each Set[b]	Each New Kit Lot[c]	Two Each Day	Other Frequency
EIA	211	174	36	63	24
WB	10	111	22	4	12
IIF	6	27	2	4	1
Other	24	34	5	2	2

[a] An EIA plate, Western blot strip or IIF slide
[b] A set of EIA plates, Western blot strips or IIF slides
[c] See explanation in Introductory Comments

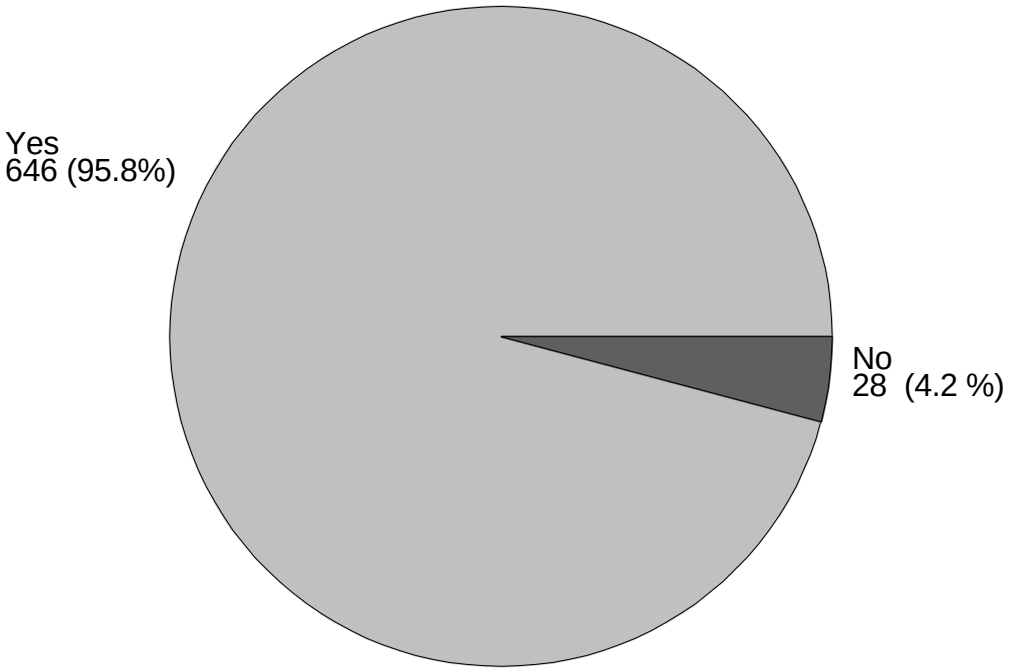
21.(a) Does your laboratory have written criteria for adopting a new test or a different manufacturer's test for HIV testing?



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

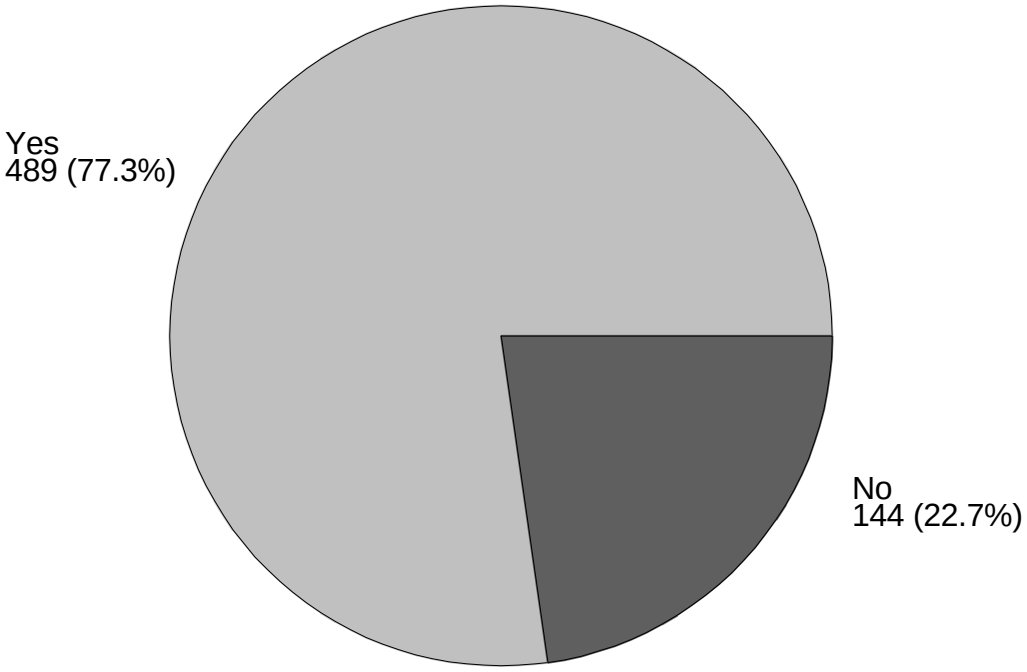


21.(c) Does your laboratory have a quality assurance plan?



N=674

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



N=633

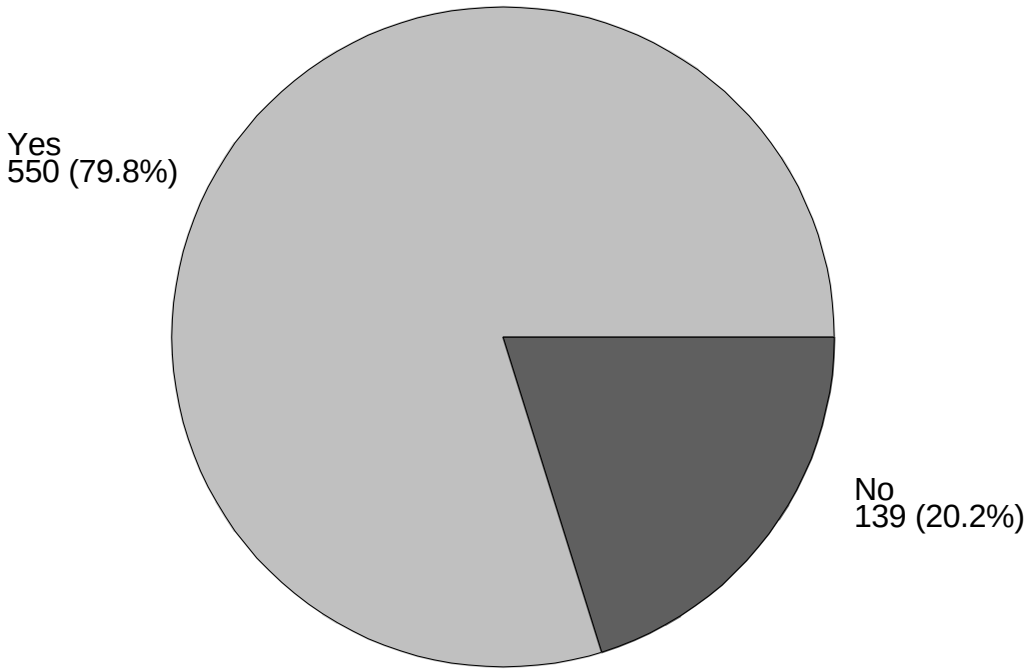
22. This question refers to the volume of HIV antibody testing performed in your laboratory. Responses should reflect the number of patient/donor specimens tested during the most recent representative month. (Round off to the nearest whole number.)

N=662

	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	7	280	247	247
10-99	105	211	203	156
100-999	300	54	48	36
1,000-9,999	204	3	2	1
10,000-99,999	45	0	0	0

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

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



N=689

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

N=541

Test Requested	Hospital	Health Department	Blood Bank	Independent	Other	Total
EIA HIV-1	6	30	7	27	14	84
EIA HIV-2	3	21	16	83	33	156
EIA HIV-1/HIV-2	4	10	6	35	14	69
WB HIV-1	21	81	29	254	43	428
WB HIV-2	6	31	20	155	49	261
IIF HIV-1	4	26	5	12	4	51
IIF HIV-2	1	7	1	11	3	23
PA	1	0	0	8	3	12
Viral RNA	12	9	3	110	21	155
Viral Culture	7	6	0	38	10	61
p24 Antigen	6	8	7	91	20	132
Other	0	4	0	8	14	26

24. 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=238

	Step 1	Step 2	Step 3	Step 4	Number of Laboratories	Percentage of Laboratories
Algorithm*	EIA-S**	EIA-D**	A		115	48.3
	EIA-S	EIA-D			32	13.4
	EIA-S	EIA-D	WB		24	10.1
	EIA-S	EIA-D	WB	A	9	3.8
	A				6	2.5
	EIA-S	EIA-D	WB/A		4	1.7
	EIA-S	WB			4	1.7
Other Algorithms					44	18.5

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 41 unique algorithms were reported

** EIA data in this table includes both manual and non-manual procedures

25. 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=209

Number of Years	EIA	WB	IIF	PCR	PA	RIPA	HTLV-I/II Antigen	Viral Culture	Other
1-3	33	12	2	7	2	2	1	0	1
4-6	29	12	0	1	1	0	1	0	1
7-9	99	15	1	2	2	2	1	2	0
10-12	33	4	0	0	1	0	0	0	0
13-15	1	0	0	0	0	0	0	0	0
>15	2	0	0	0	0	0	0	0	0

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

N=210

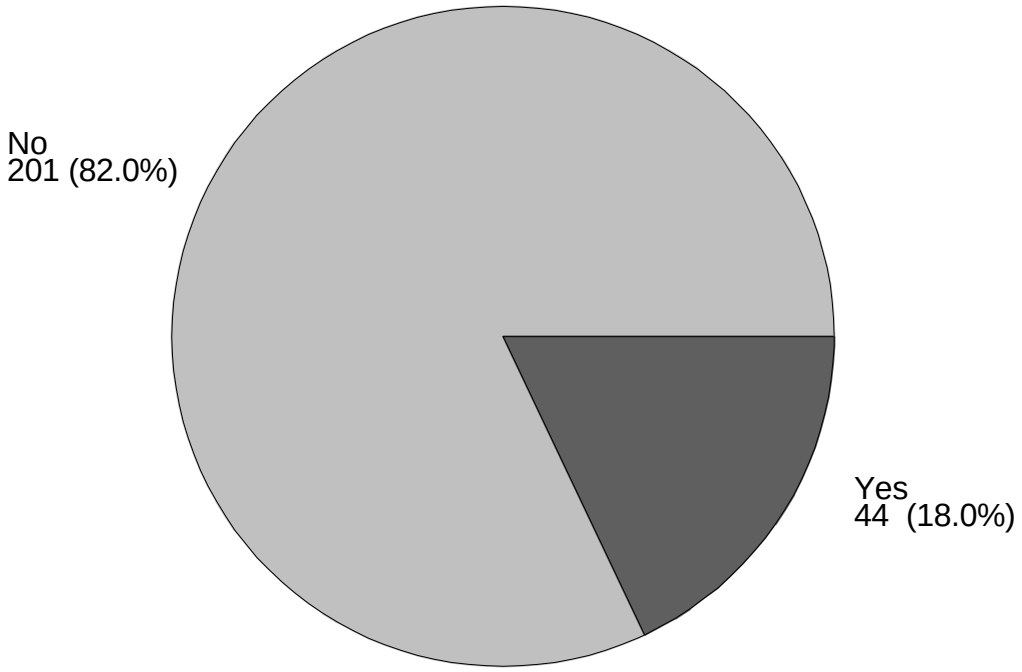
Number of Employees	EIA	WB	IIF	PCR	PA	RIPA	HTLV-I/II Antigen	Viral Culture	Other
1-2	19	14	2	6	1	1	1	1	1
3-4	44	17	0	3	1	3	0	0	0
5-6	43	5	0	0	0	0	2	1	0
7-8	29	1	0	0	0	0	0	0	1
9-10	28	1	0	1	1	0	0	0	0
>10	35	1	0	0	1	0	0	0	0

26. 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 = 229

Type of procedure	EIA	WB	IIF	Other
In-house written protocol	184	33	2	9
Manufacturer's insert	201	33	3	7
Provided by the State Health	4	1	0	0
Other sources	7	2	0	1

27.(a) Does your laboratory perform HTLV Western blot testing?



N=245

27.(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 one.)

N=44

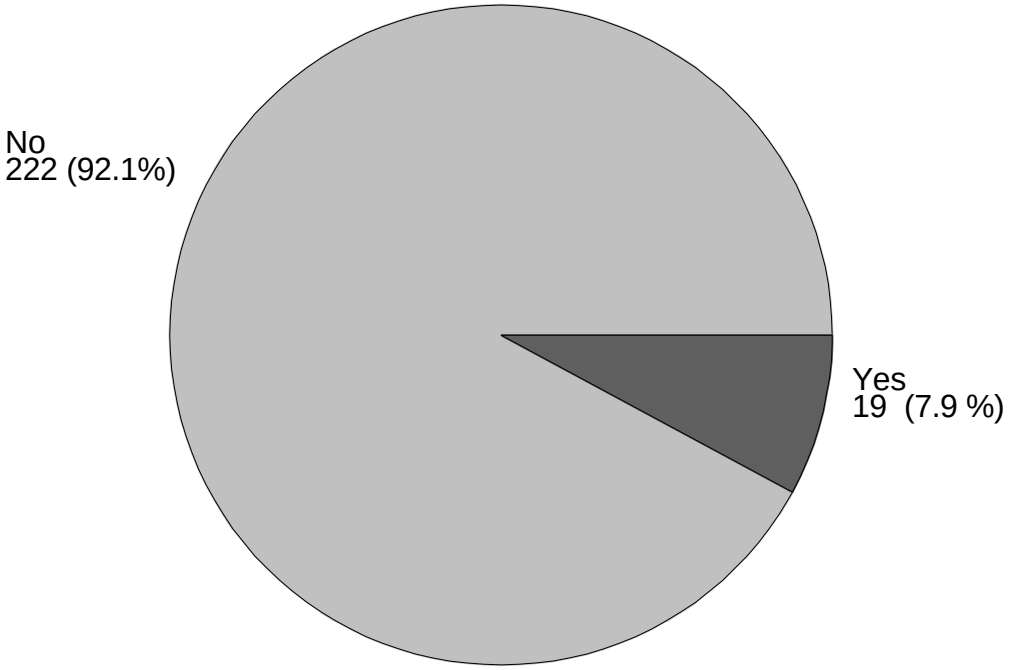
Band Patterns	Number of Laboratories	Percentage of Laboratories
Other	18	40.9
p24 and gp46 or r21e (recombinant envelope protein)	11	25.0
One protein from each of the viral gene product groups: gag (19,p24) and env (gp21, gp46, gp61/68)	7	15.9
p19 or p24, and gp46 or gp61/68	4	9.1
Any HTLV-I/II specific protein band(s)	3	6.8
p24 and gp46 or gp61/68	1	2.3

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

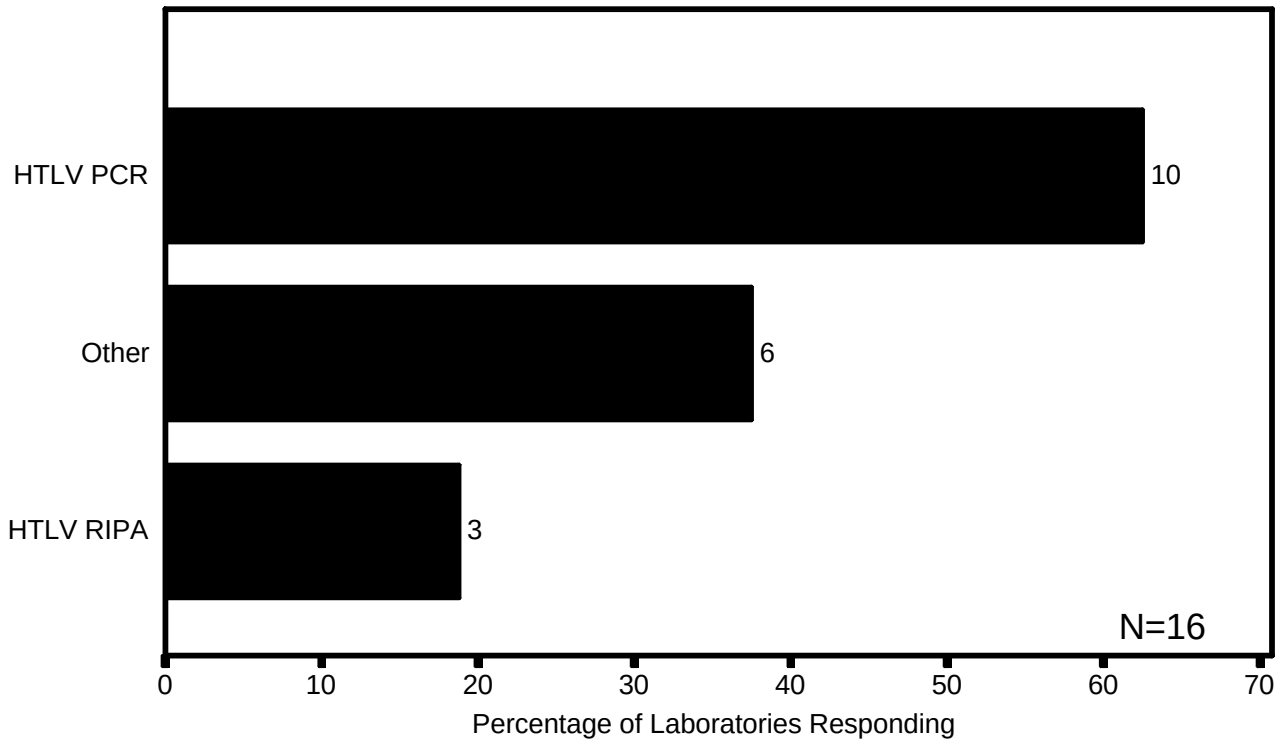
N=43

Band Patterns	Number of Laboratories	Percentage of Laboratories
No bands present	23	53.5
No HTLV-I/II specific protein band(s) (i.e., 19, 21/22, 24, 26, 36, 46, 53/55, 61/68)	19	44.2
Other	1	2.3

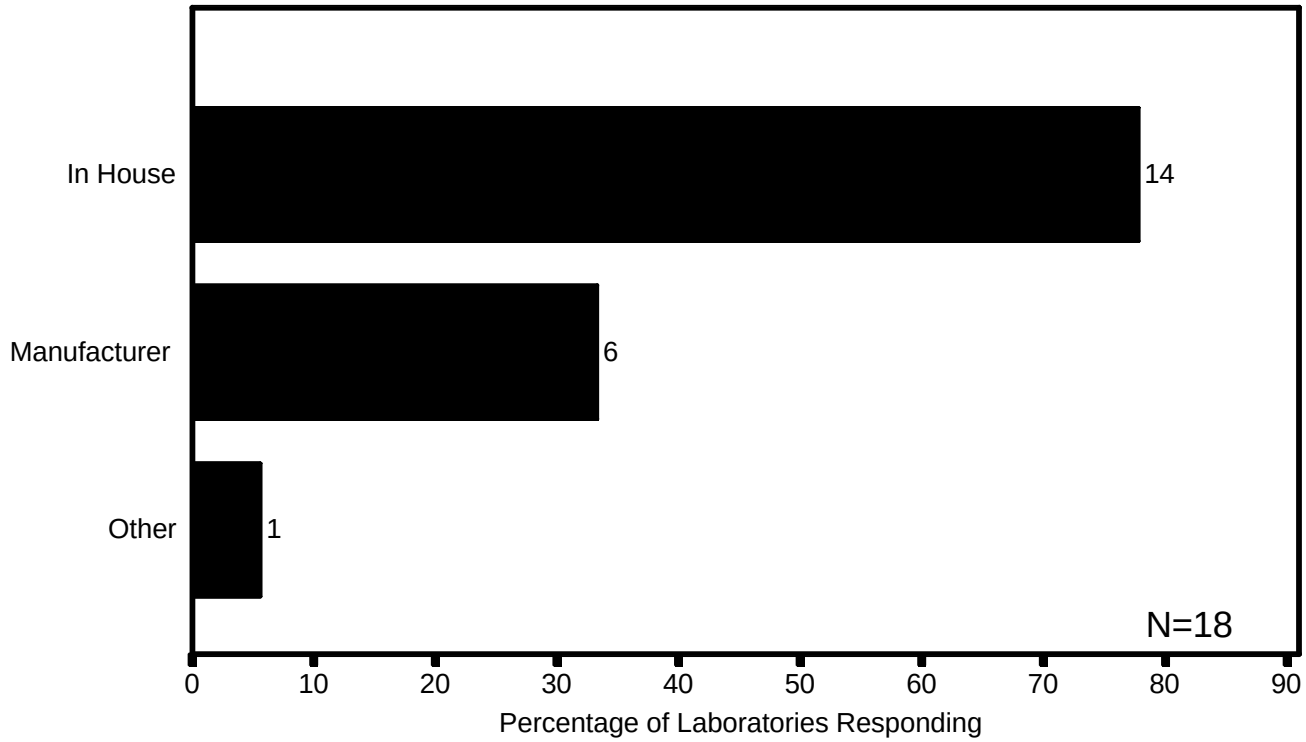
28.(a) Do you perform an HTLV-I/II antibody test other than EIA, WB, or IIF, to detect HTLV-I/II infection?



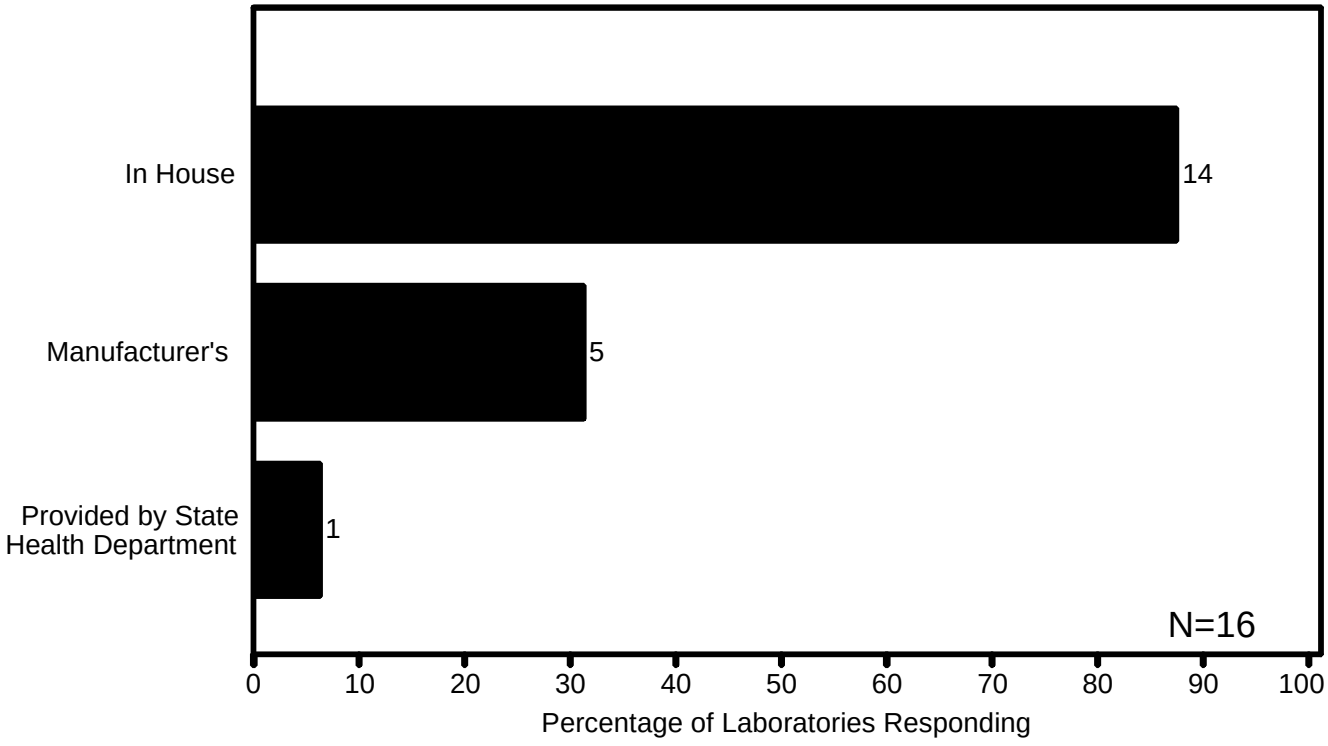
28.(b) If yes, indicate below the other tests performed in your laboratory (Check all that apply.):



28.(c) Source of reagents (Check all that apply.):



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



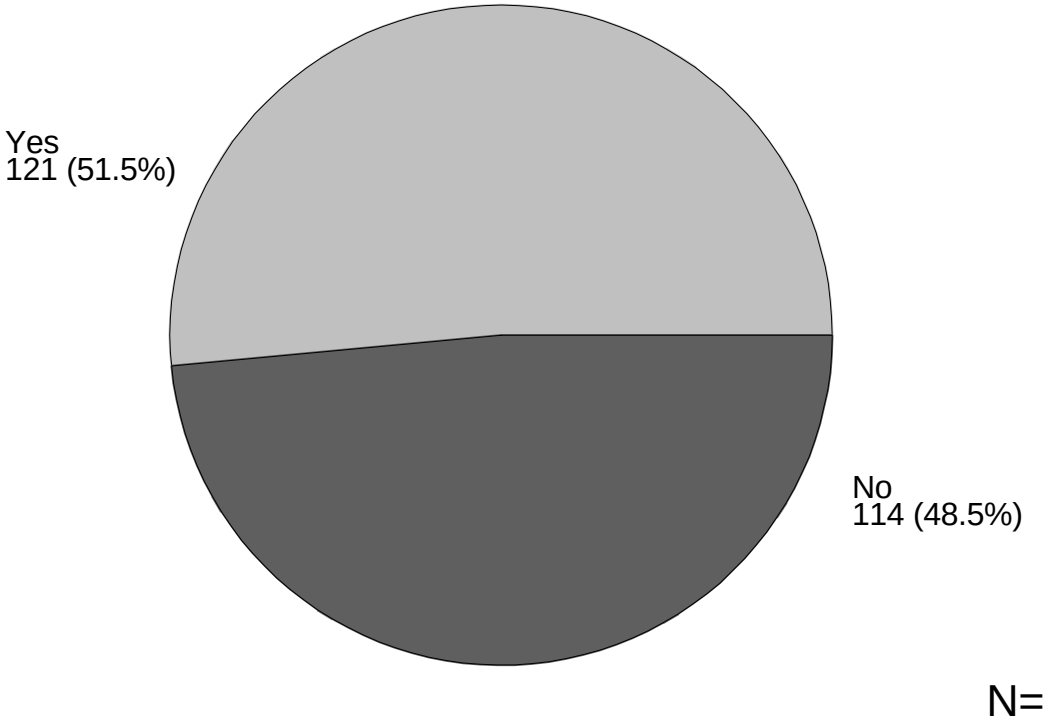
29. Please indicate the frequency with which your laboratory uses HTLV-I/II control sera/plasma (other than kit manufacturer controls) for each of the test methods below (Check all that apply.):

N=151

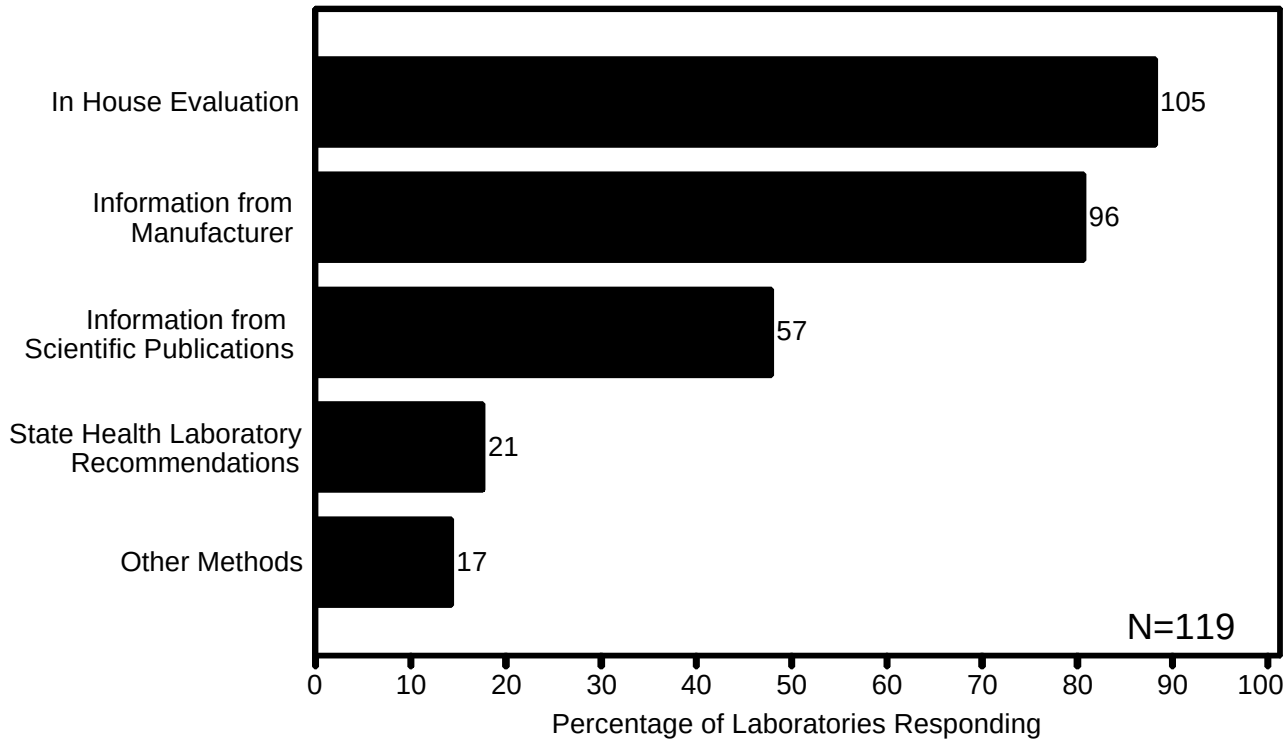
Test Method	Each Test [a]	Each Set [b]	Two Each Day	Other Frequency
EIA	63	59	16	15
WB	2	21	1	3
IIF	0	3	0	0
Other	4	5	2	0

[a] an EIA plate, Western blot strip or IIF slide
[b] A set of EIA plates, Western blot strips or IIF slides

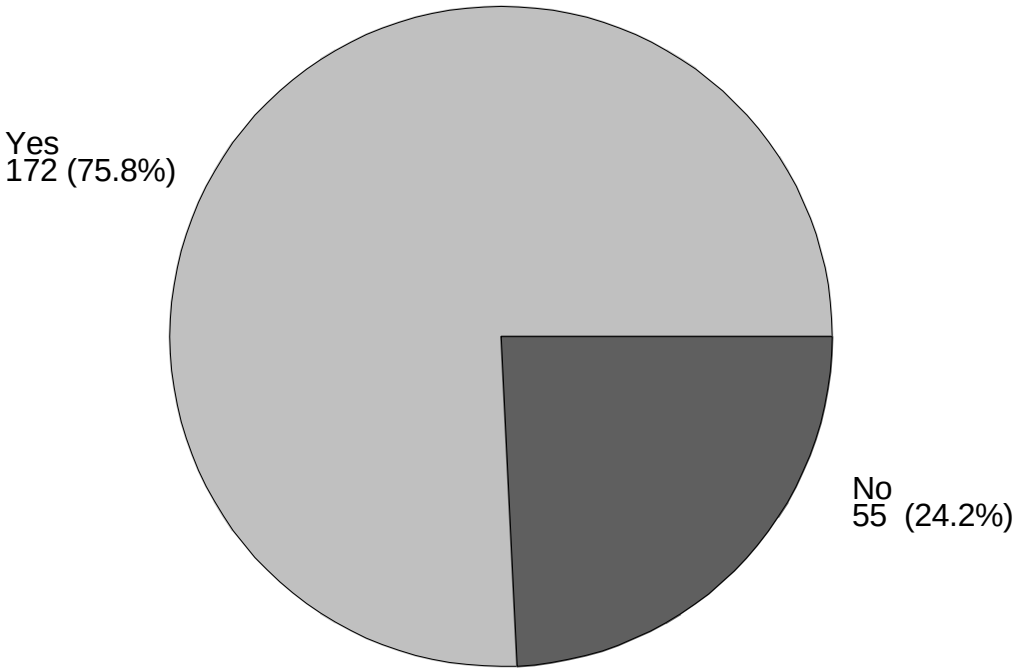
30.(a) Does your laboratory have written criteria for adopting a new test or a different manufacturer's test for HTLV-I/II testing?



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

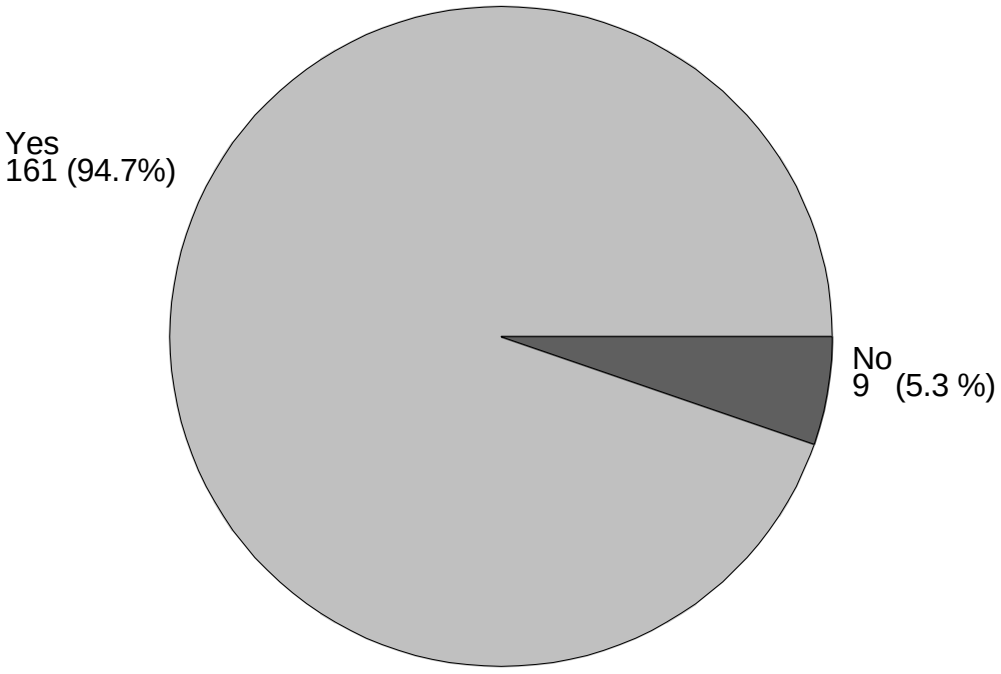


30.(c) Does your laboratory have an HTLV quality assurance plan?



N=227

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



N=170

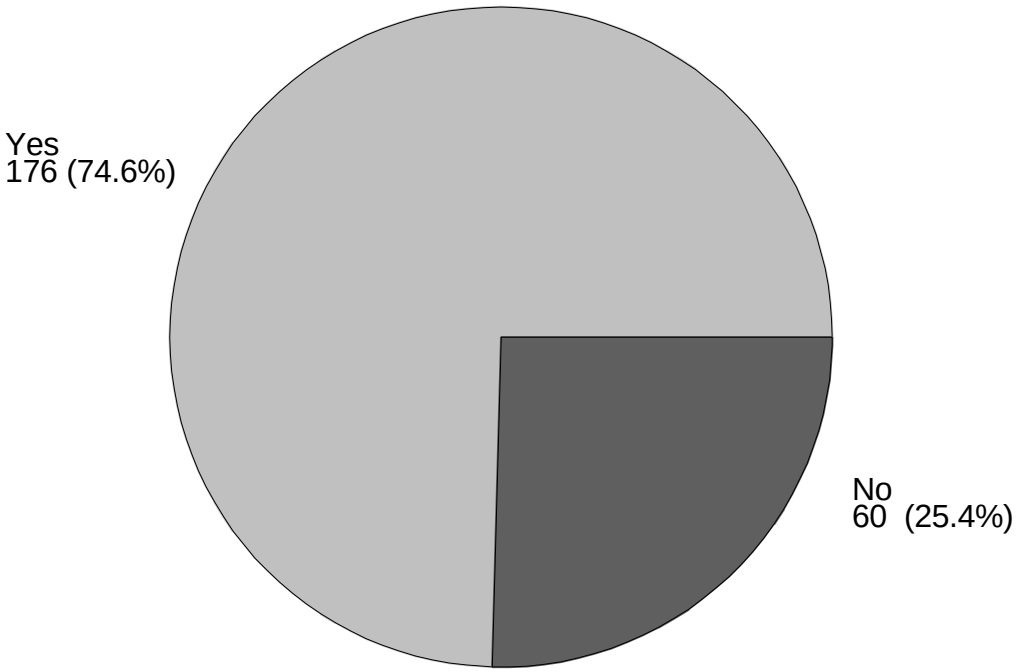
31. This question refers to the volume of HTLV-I/II antibody testing performed in your laboratory. Responses should reflect the number of patient/donor specimens tested during the most recent representative month. (Round off to the nearest whole number.)

N=215

	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	81	68	40
10-99	57	26	27	9
100-999	65	8	6	4
1,000-9,999	59	0	0	0
10,000-99,999	18	0	0	0

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

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



N=236

32.(b) Please indicate the additional testing requested and identify the types of laboratories to which HTLV-I/II specimens are referred for these additional tests (Check all that apply.):

N=175

Test Requested	Hospital	Health Department	Blood Bank	Independent	Other	Total
EIA	1	3	2	20	4	30
WB	3	8	17	112	19	159
IIF	0	3	0	3	0	6
PA	0	0	0	1	2	3
RIPA	1	1	2	49	4	57
PCR	3	3	0	14	6	26
Viral Culture	1	0	0	5	2	8
Antigen	1	0	0	3	1	5
Other	0	0	0	1	1	2