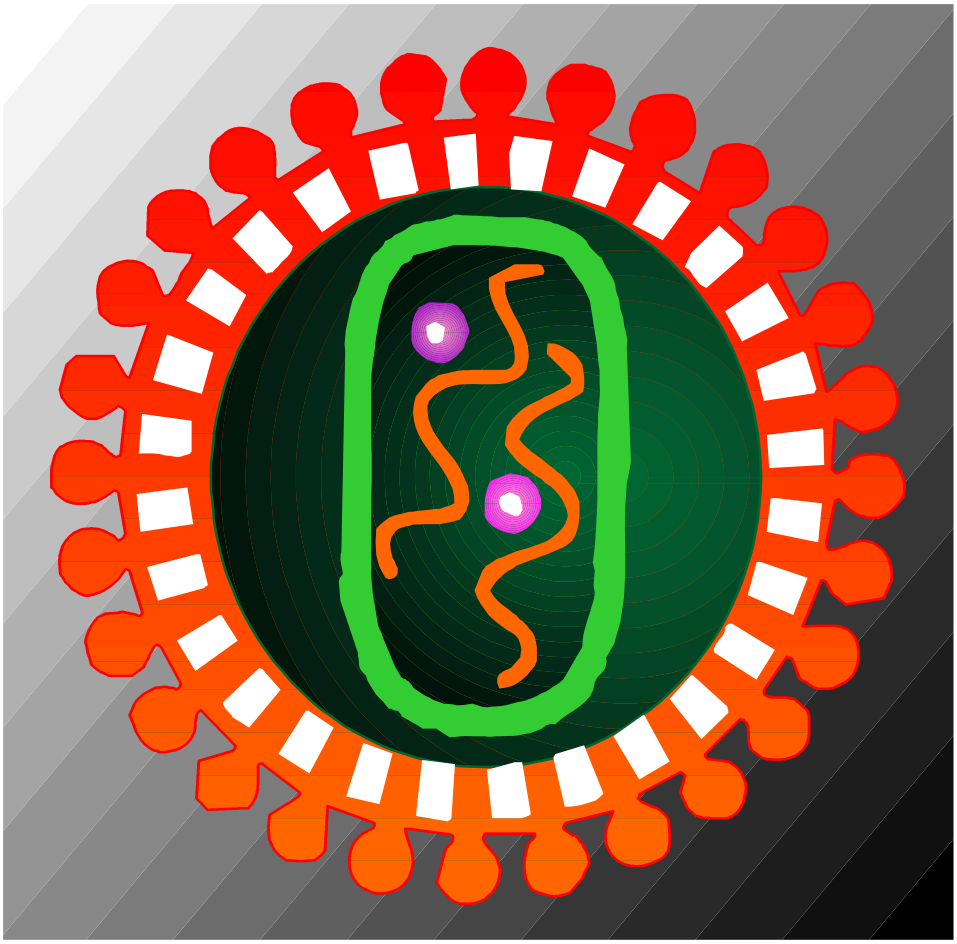
Results of the 1995 Retroviral Testing Survey Questionnaire Sent to Laboratories Participating In the Model Performance Evaluation Program



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

Results of a 1995 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:

Public Health Practice Program Office.....Edward L. Baker, M.D., M.P.H.
Director

Division of Laboratory Systems.....Carlyn L. Collins, M.D., M.P.H.
Director

Laboratory Practice Assessment Branch.....Thomas L. Hearn, Ph.D.
Chief

The material in this report was developed and prepared by:

Model Performance Evaluation Program (MPEP).....William O. Schalla, M.S.
Chief

MPEP Retroviral Performance Evaluation.....Sharon O. Blumer, M.S.
MPEP Retroviral Project Coordinator

Information about this report should be addressed to the Model Performance Evaluation Program by calling (770) 488-4147 or (770) 488-4366.

Introductory Comments on the Model Performance Evaluation Program 1995 Retroviral Questionnaire Survey Results

Of the 987 laboratories receiving the Model Performance Evaluation (MPEP) retroviral questionnaire survey mailed September 25, 1995, 770 (81.3%) responded. Aggregate data from selected questions believed to be of most interest to participating laboratories 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 1 and 2, the number of laboratories enrolled in the MPEP, by country and in the United States and Territories, reflects the enrollment as of April 28, 1996 and does not necessarily reflect the MPEP enrollment at the time this survey was mailed.

Please note that all parts of questions 6 and 7 were worded differently than in previous questionnaire surveys to reflect current regulatory requirements related to the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) as published in CFR 42 Part 493. These changes were primarily related to the education and certification requirements of the laboratory director and supervisor.

In question 6b, the academic discipline of Microbiology was inadvertently omitted as a response selection in the questionnaire. Nearly 50% of the responses in the "Other" category were specified as "Microbiology"; therefore, this response was subtracted from the "Other" category and presented as a unique response in the graphic. Similarly, in question 6c, the American Board of Pathology was inadvertently omitted from the questionnaire as a response selection for an organization awarding board certification. More than 50% of the responses in the "Other" category were specified as "American Board of Pathology"; therefore, this response was subtracted from the "Other" category and presented as a unique response in the graphic.

For questions 15a, 15b, and 24 responses reflecting routine testing combinations associated with algorithms are reported in a table format. Although many laboratories (approximately 60%) described common algorithms, many laboratories continue to have unique testing combinations for detecting HIV and HTLV antibody. These various testing combinations are grouped as "Other Algorithms" in the tables reporting the responses to questions 15a, 15b, and 24.

Please note that in questions 16 and 24 the first column reflects a range of months (or employees) while the remaining columns reflect the number of laboratories performing specific tests for the range of months, 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.

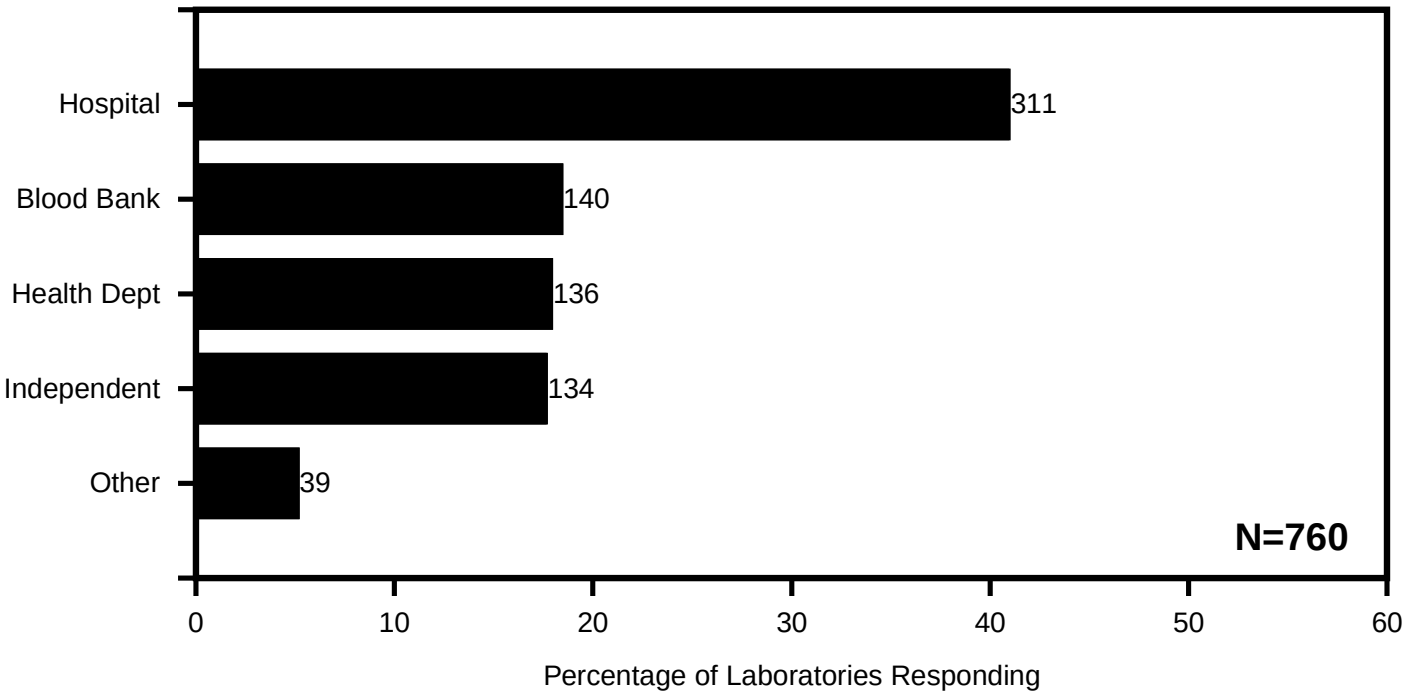
Questions 20 and 29 were revised from previous questionnaire surveys to reflect the frequency with which external quality control samples are used and is related to CLIA-88 regulations.

Number of MPEP laboratories by country

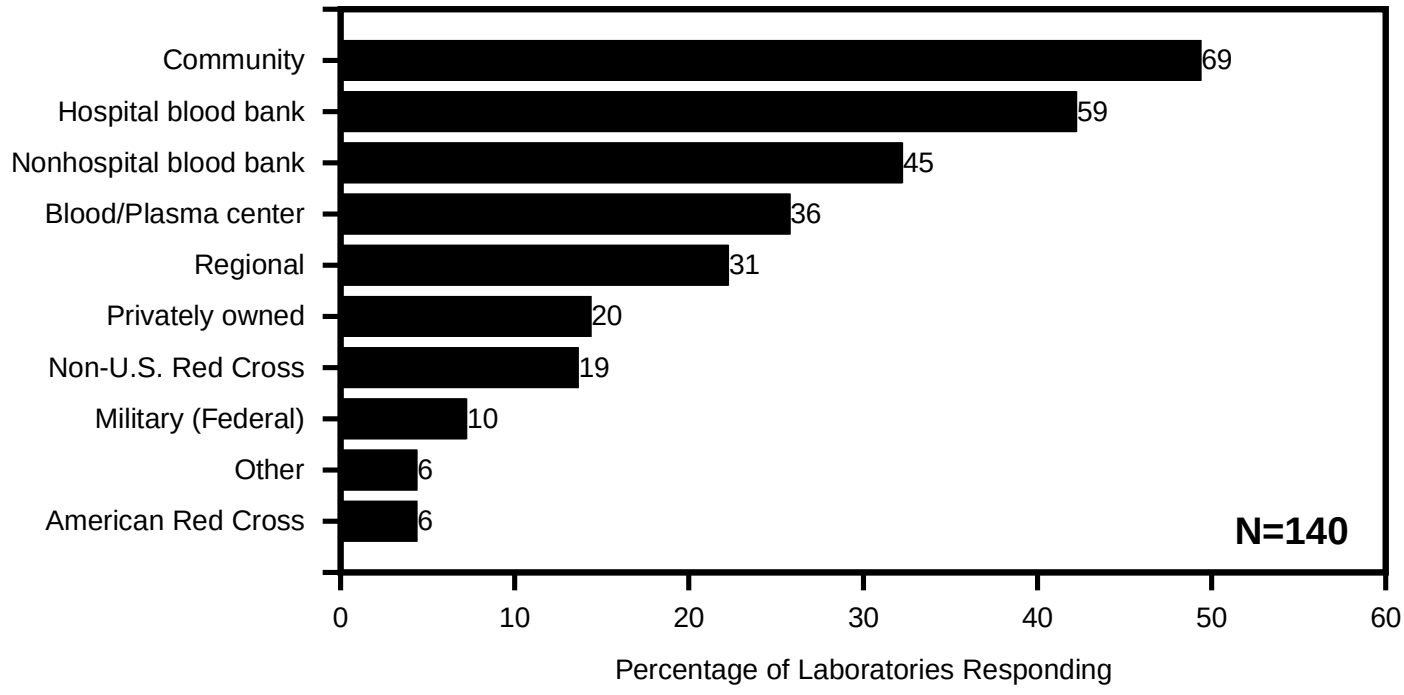
N = 986 Country	Number of Laboratories		Country	Number of Laboratories		Country	Number of Laboratories
Argentina	5		Guatemala	1		Saudi Arabia	2
Australia	6		Honduras	2		Scotland	1
Austria	2		Hong Kong	2		South Africa	3
Bahamas	1		Hungary	1		Spain	3
Barbados	1		India	1		Sri Lanka	1
Belgium	3		Ireland	1		St. Kitts/ Nevis	1
Bolivia	1		Israel	1		Suriname	1
Brazil	3		Italy	1		Switzerland	3
Burkina Faso	1		Jamaica	1		Taiwan	2
Burma	1		Japan	2		Tanzania	2
Canada	19		Kenya	1		Thailand	2
Central African Rep.	1		Korea	1		The Netherlands	1
Chile	2		Malaysia	2		Trinidad/Tobago	3
Colombia	1		Mexico	1		Uganda (East Africa)	1
Costa Rica	3		Morocco	1		Ukraine	1
Cote d'Ivoire	1		New Zealand	1		United Arab Emirates	3
Croatia	2		Nicaragua	1		United States	822
Denmark	3		Nigeria	1		Uruguay	1
Dominican Republic	3		Norway	1		US Territory	22
Ecuador	2		Panama	1		Venezuela	2
Egypt	1		Paraguay	1		Western Samoa	1
El Salvador	1		Peru	3		Vietnam	1
England	3		Philippines	2		Western Samoa	1
Ethiopia	1		Portugal	1		Yugoslavia	1
Germany	5		Republic of Singapore	1		Zambia	1

Number of MPEP Laboratories in the United States and Territories

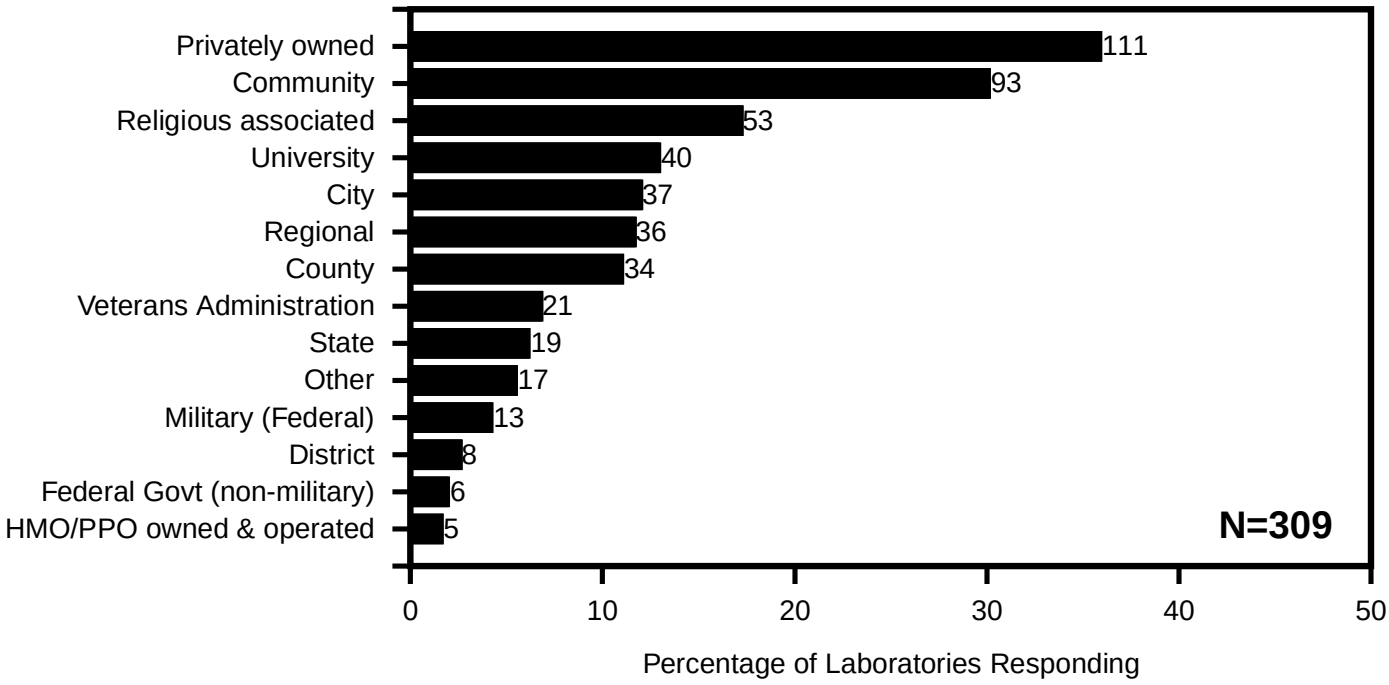
4.(a) Please use the following to describe the primary classification of your laboratory in regard to retroviral testing (Check only one.):



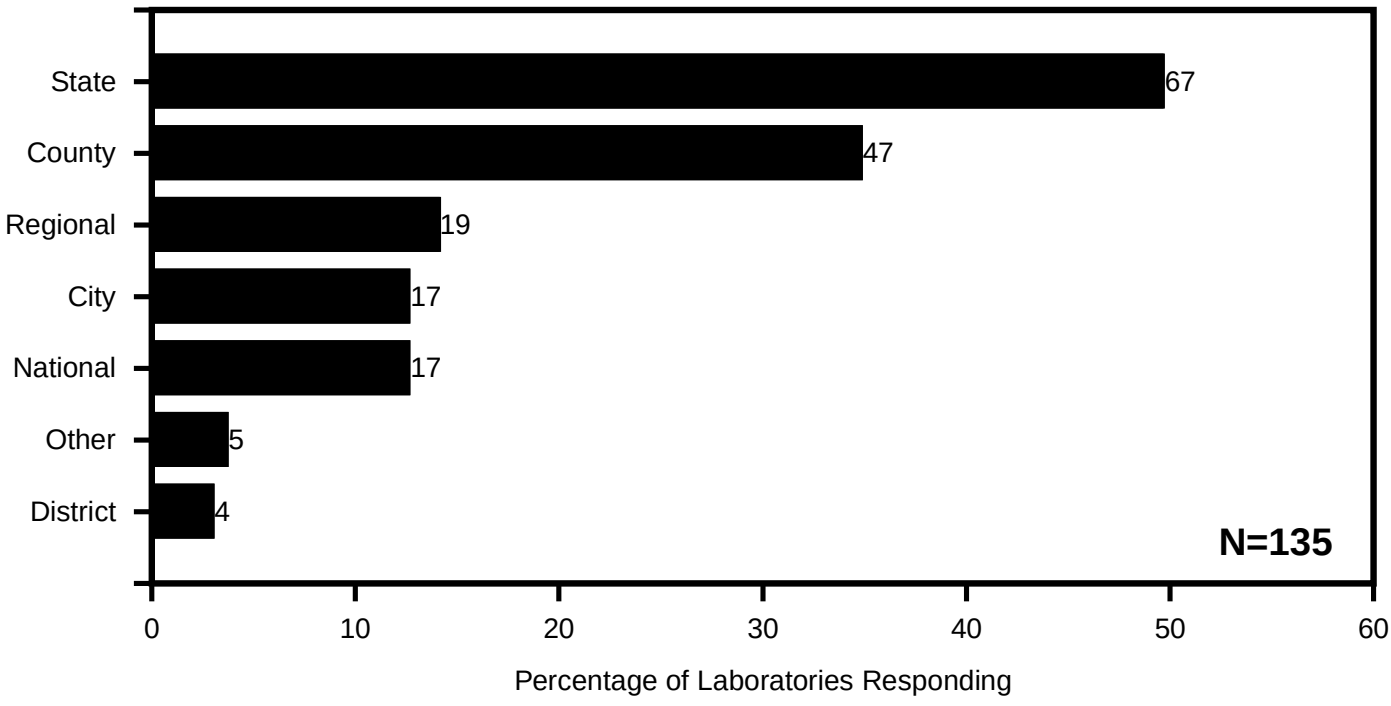
4.(b) If you selected BLOOD BANK in 4(a), please further describe your retroviral testing laboratory (Check all that apply within your Blood Bank laboratory classification):



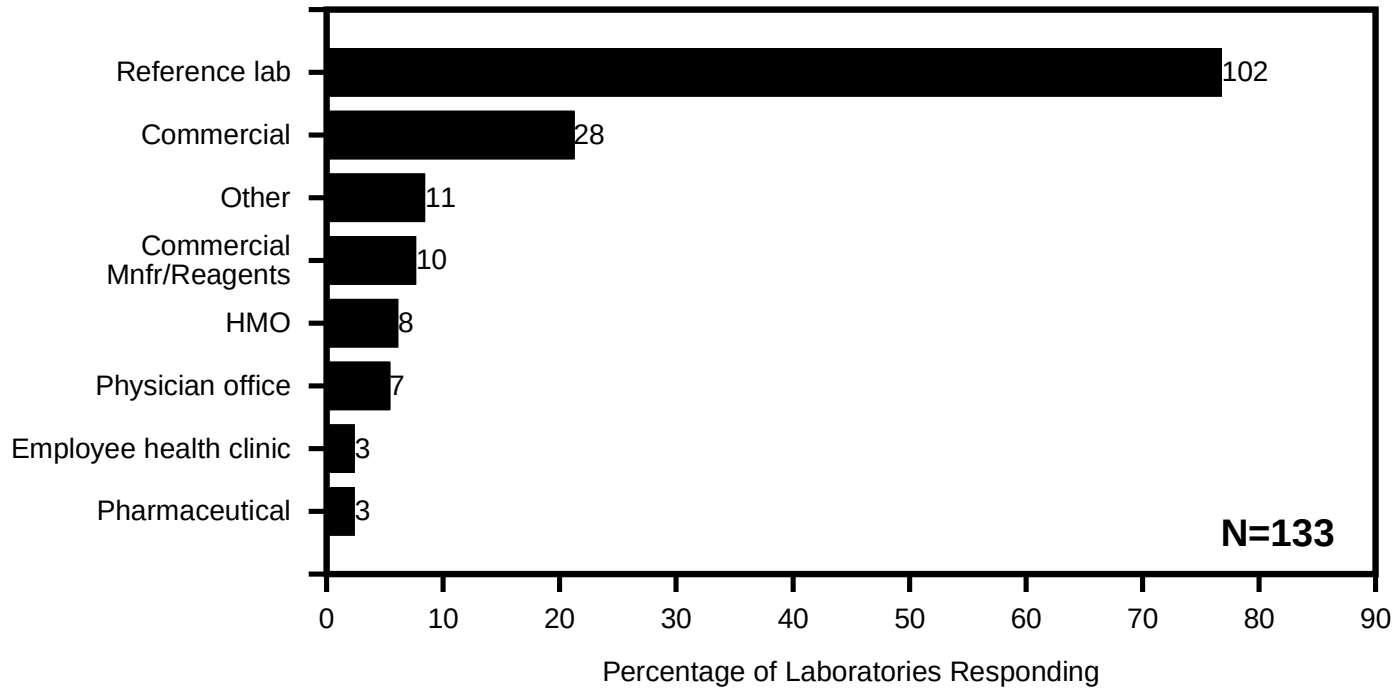
4.(c) If you selected HOSPITAL in 4(a), please further describe your retroviral testing laboratory (Check all that apply within your Hospital laboratory classification):



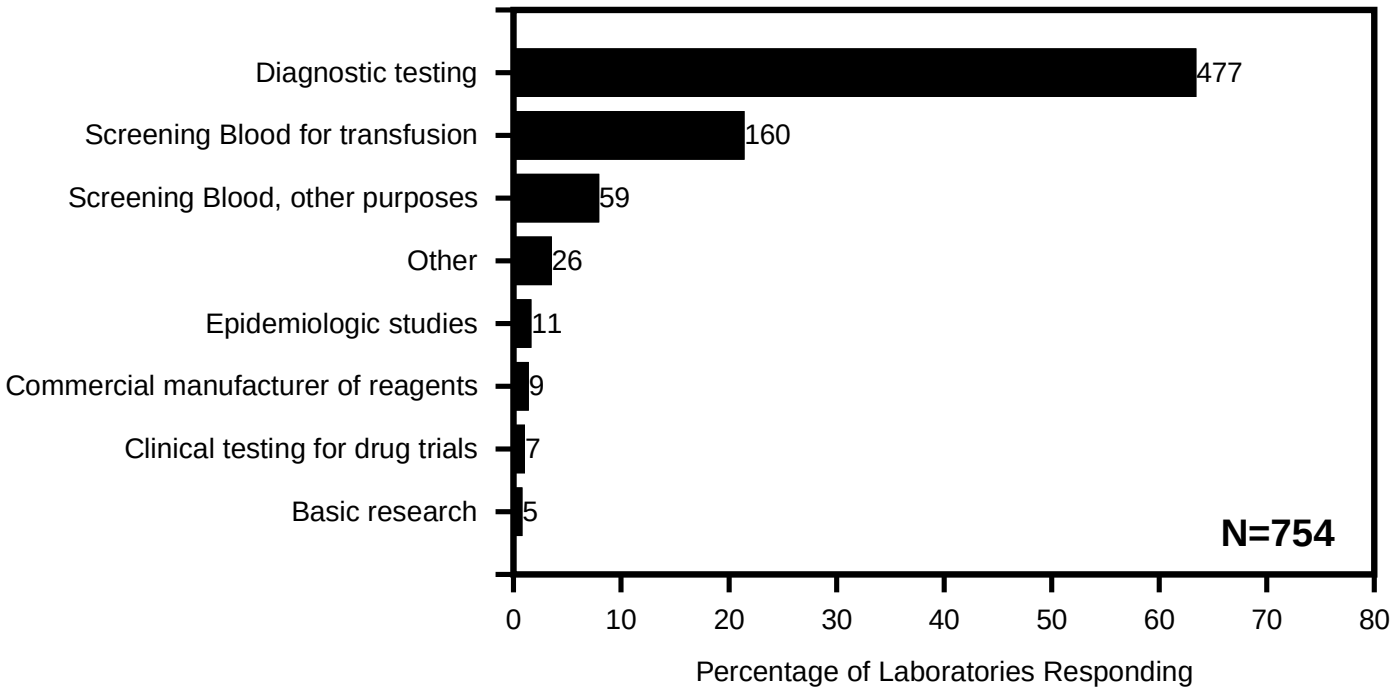
4.(d) If you selected HEALTH DEPARTMENT in 4(a), please further describe your retroviral testing laboratory (Check all that apply within your Health Department laboratory classification):



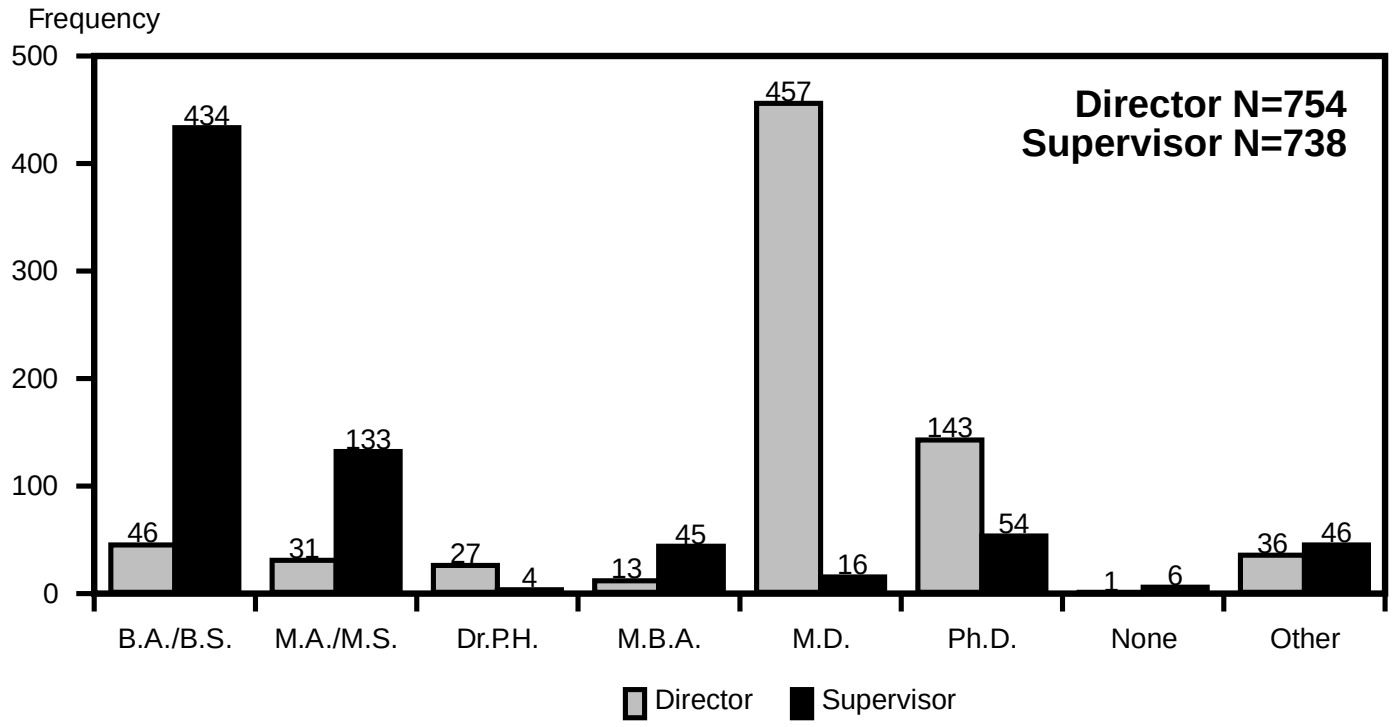
4.(e) If you selected INDEPENDENT in 4(a), please further describe your retroviral testing laboratory (Check all that apply within your Independent laboratory classification):



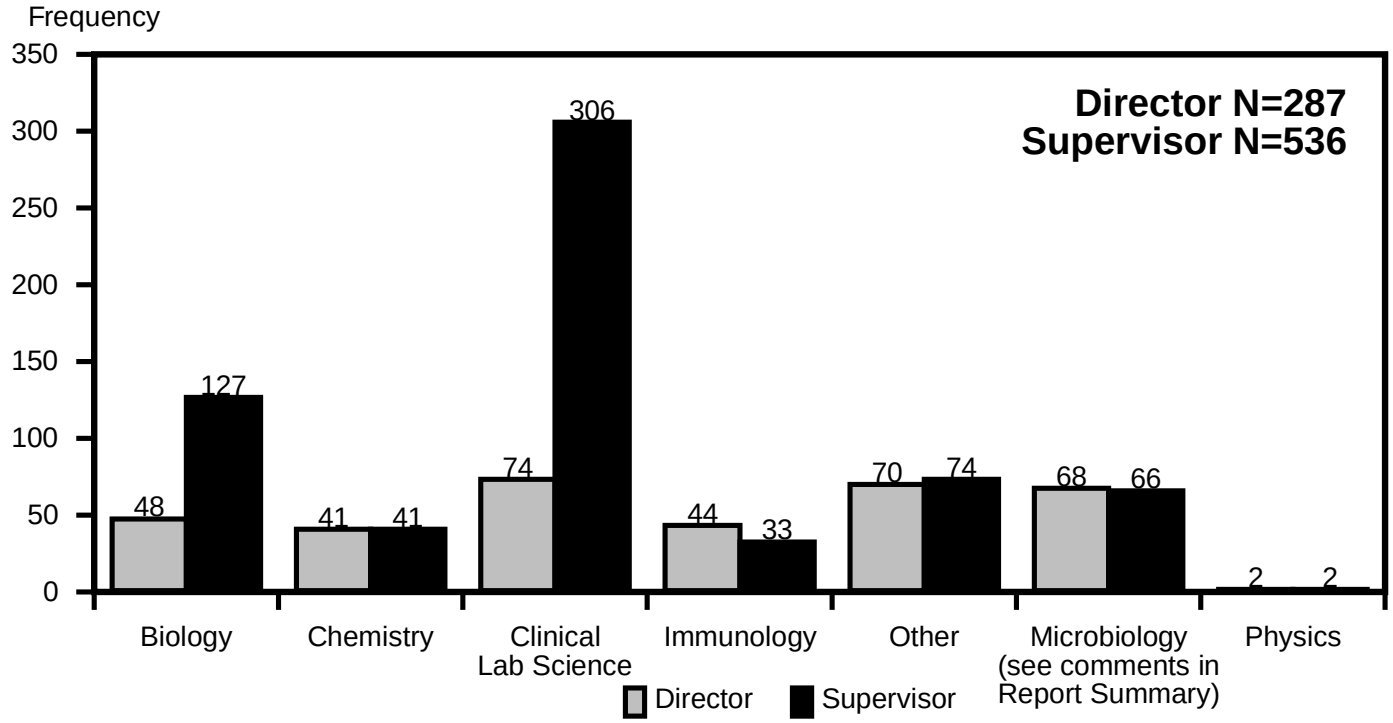
5. What is the primary purpose of your retroviral testing operation? (Check only one.)



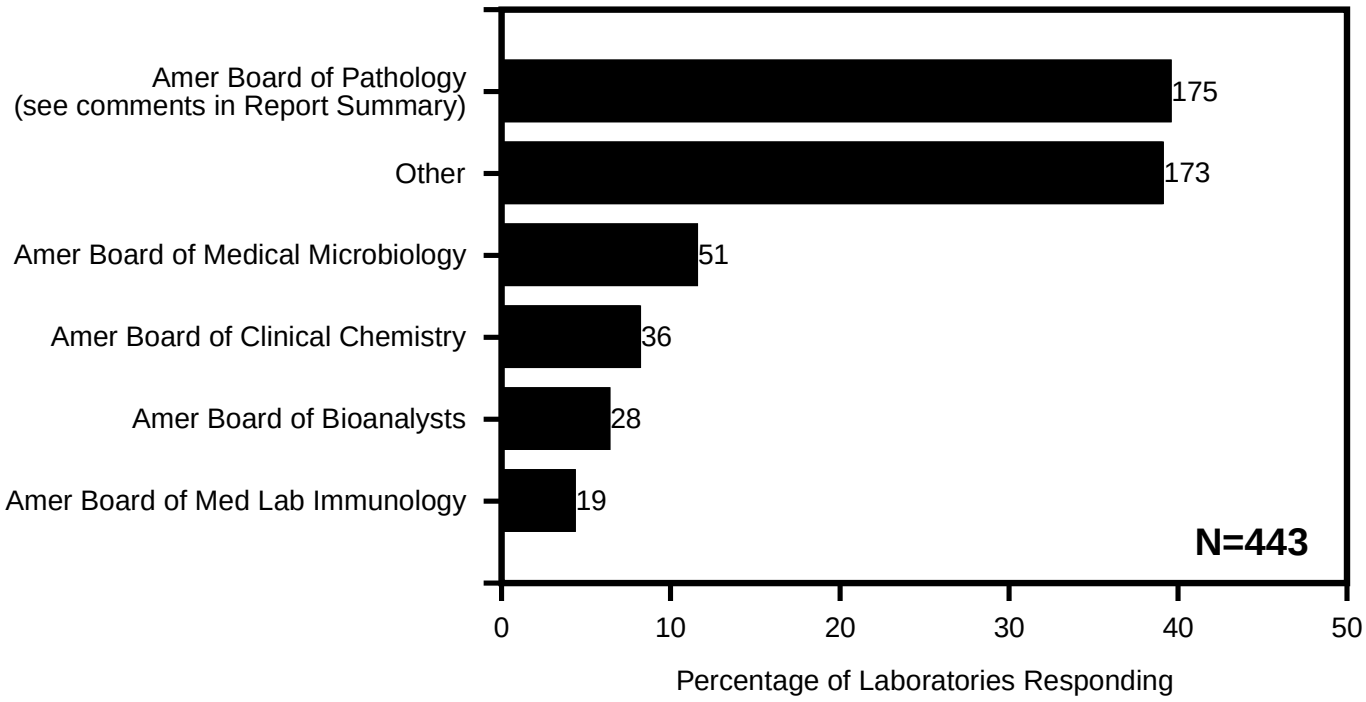
6.(a) Please indicate the highest degree that has been awarded to your Laboratory Director and Laboratory Supervisor (Check only one degree for each person.):



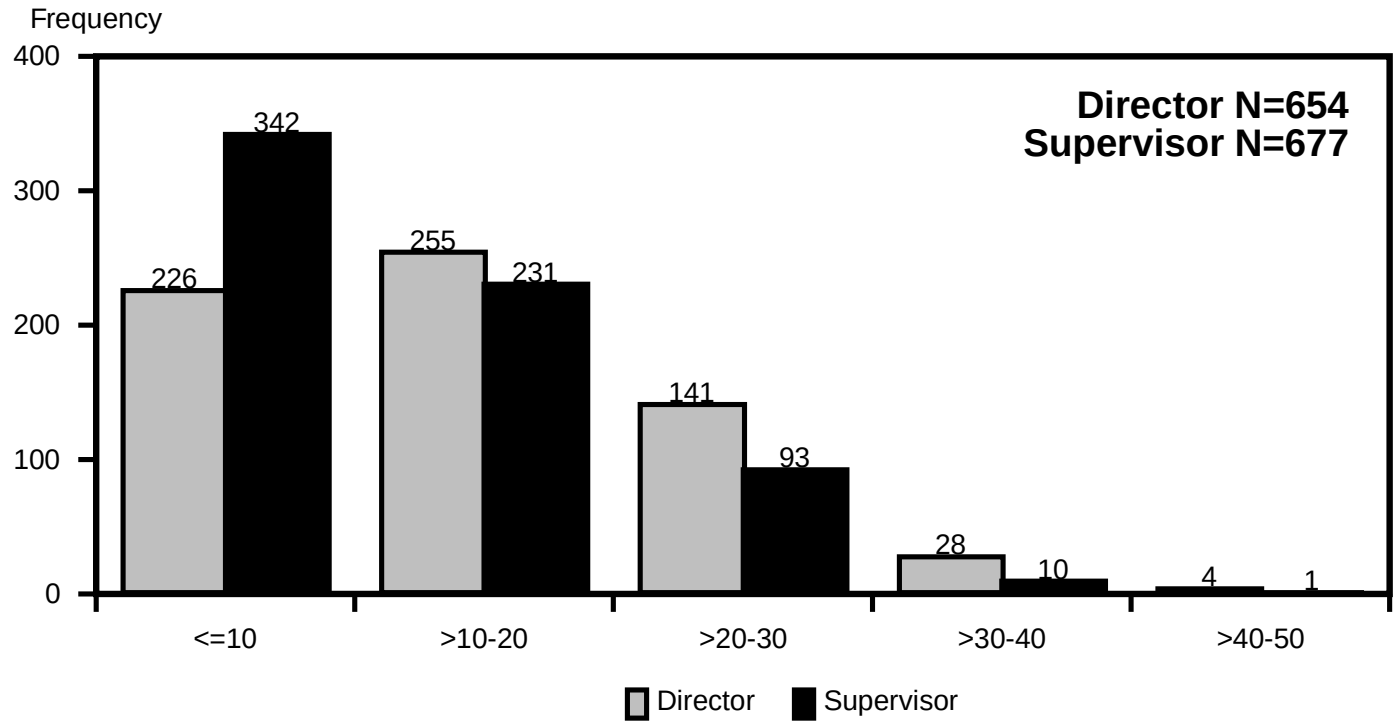
6.(b) If your Laboratory Director or Laboratory Supervisor has a degree other than M.D. or D.O., please indicate the academic discipline in which the degree was awarded (Check all that apply.):



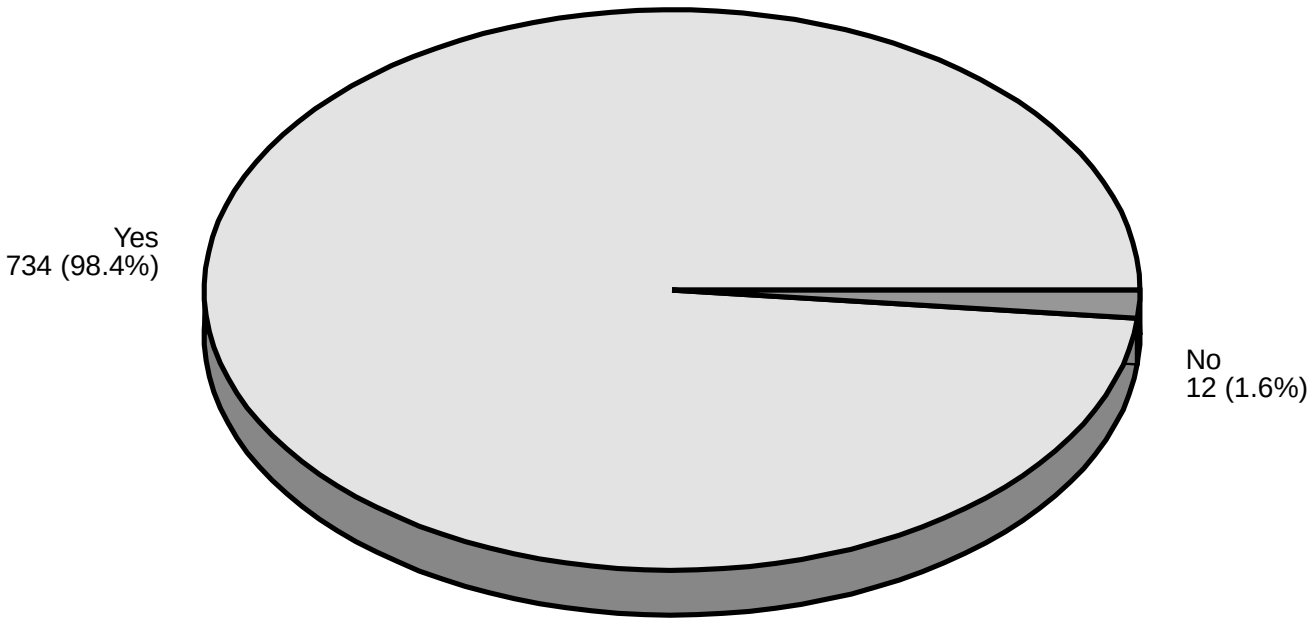
6.(c) What organization(s) have awarded board certification to your Laboratory Director ? (Check all that apply):



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

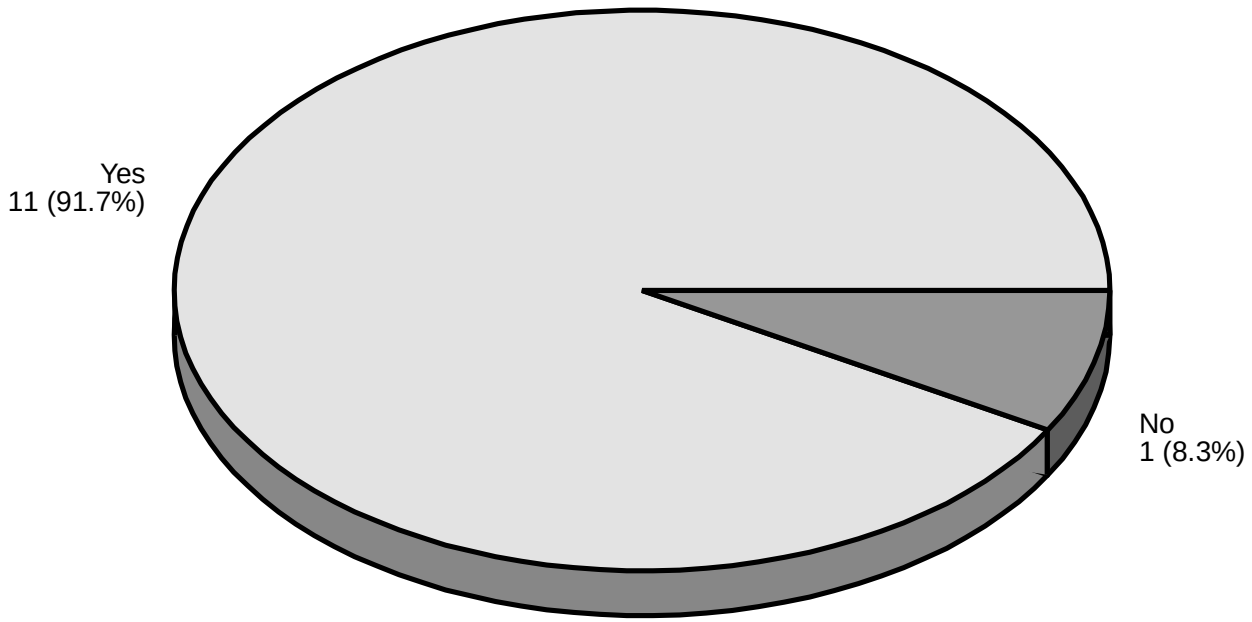


6.(e) Is your Laboratory Supervisor available to provide supervision on-site?



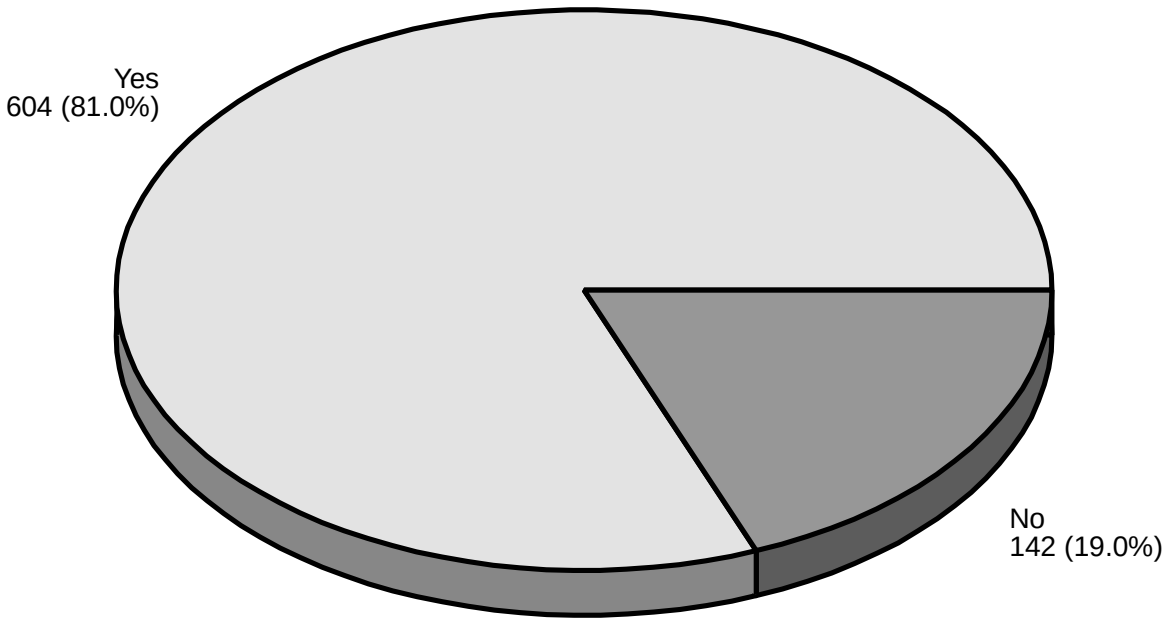
N=746

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



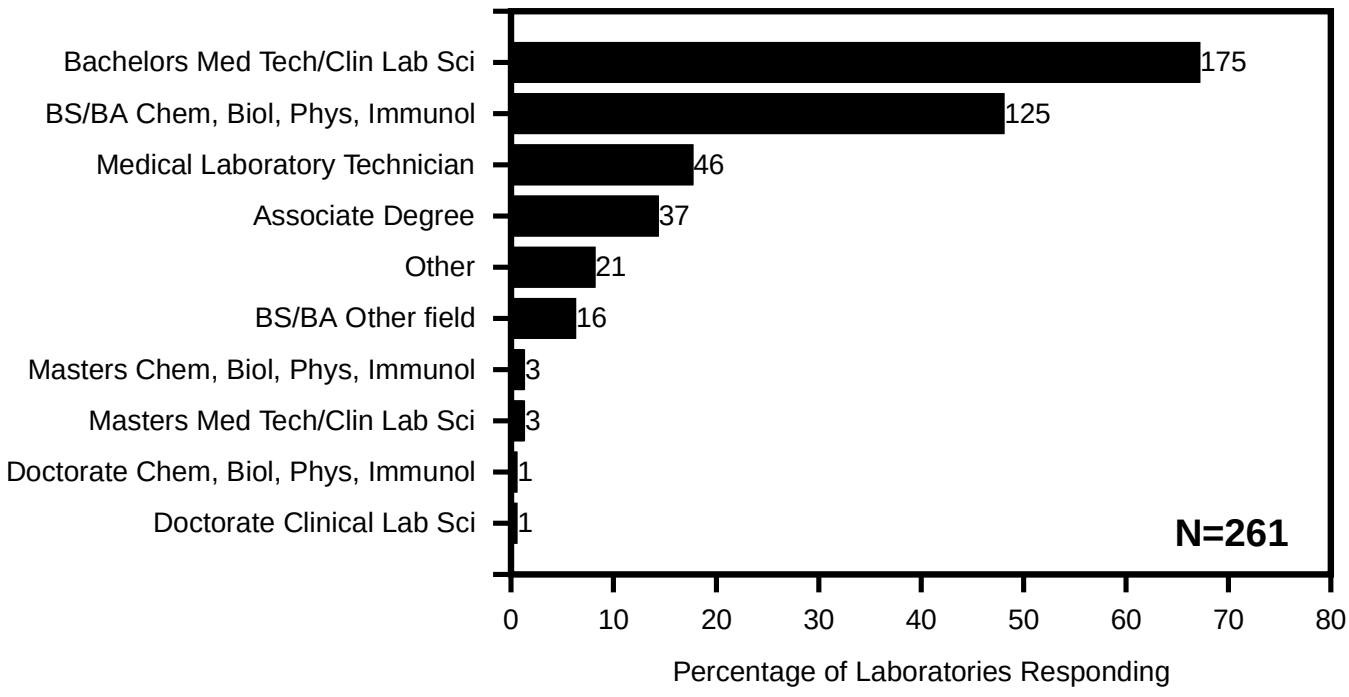
N=12

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

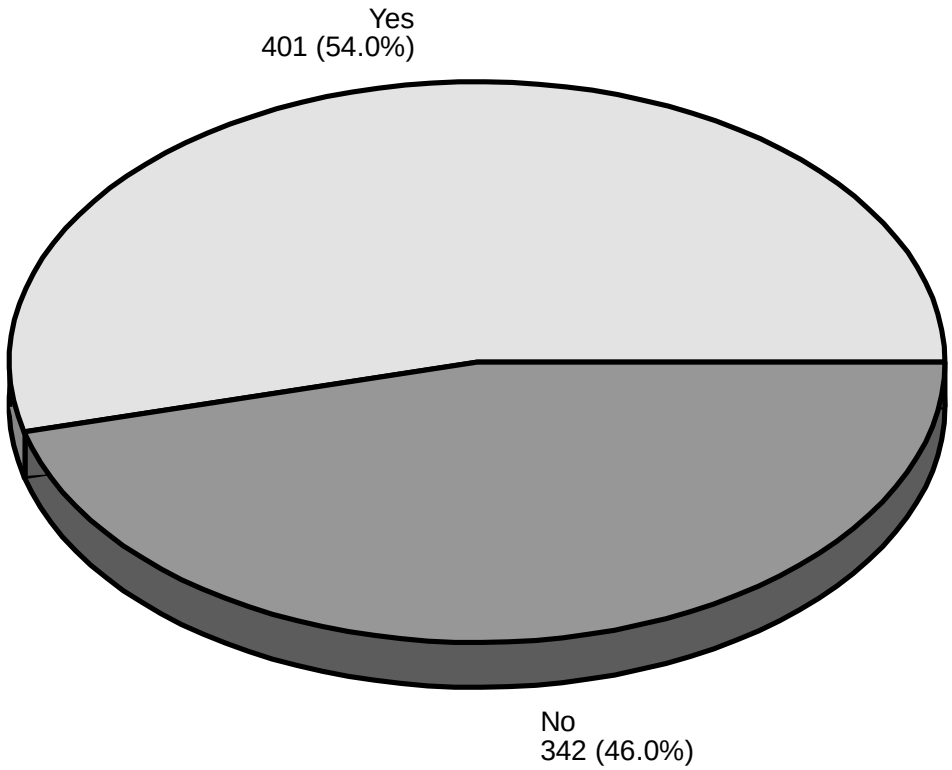


N=746

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

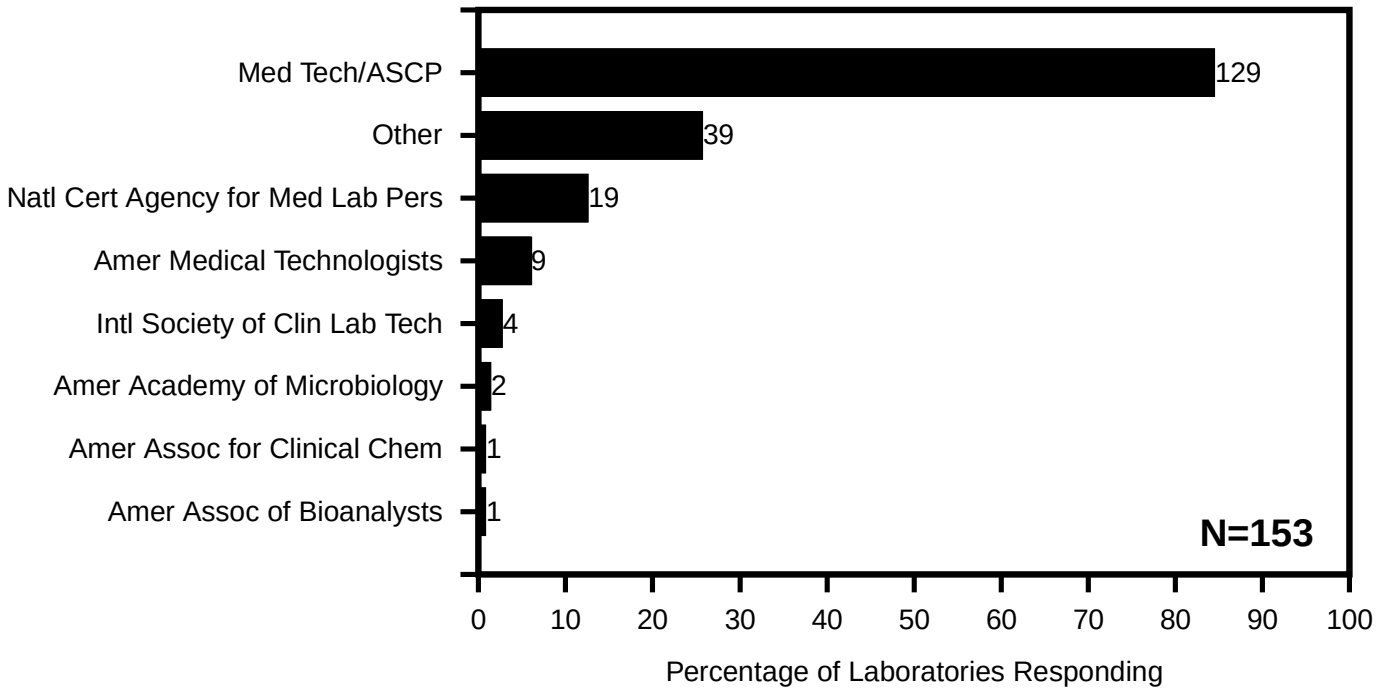


7.(c) Does your laboratory require that your retroviral testing personnel have professional certification?

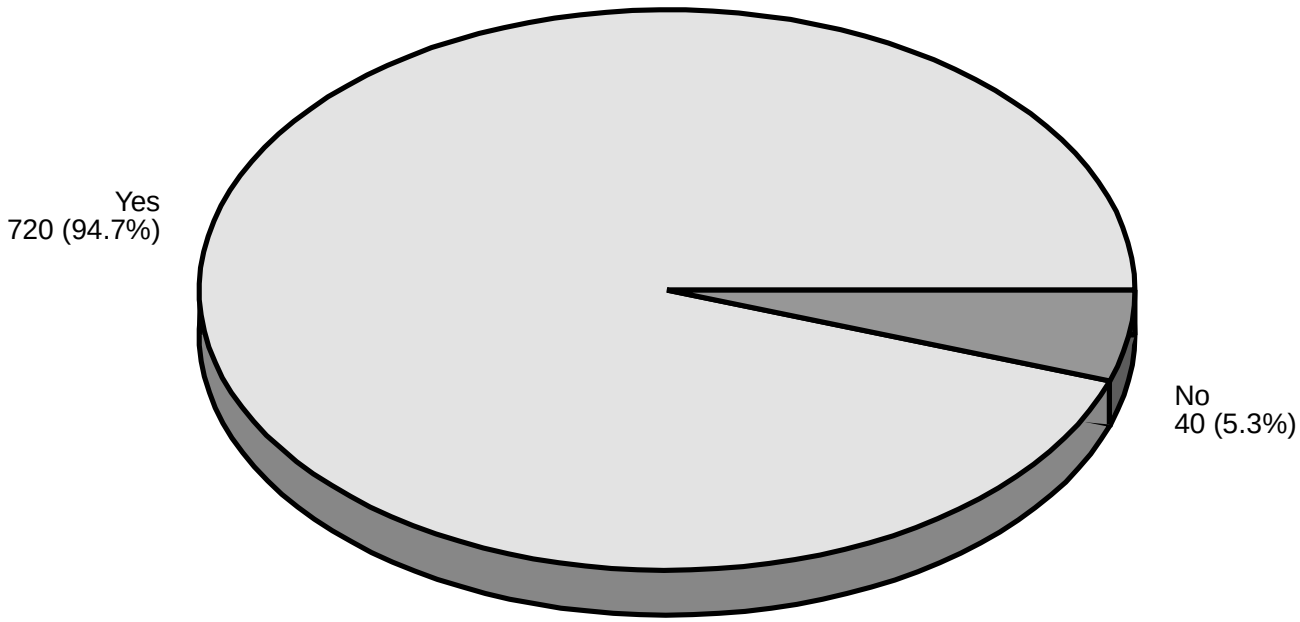


N=743

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

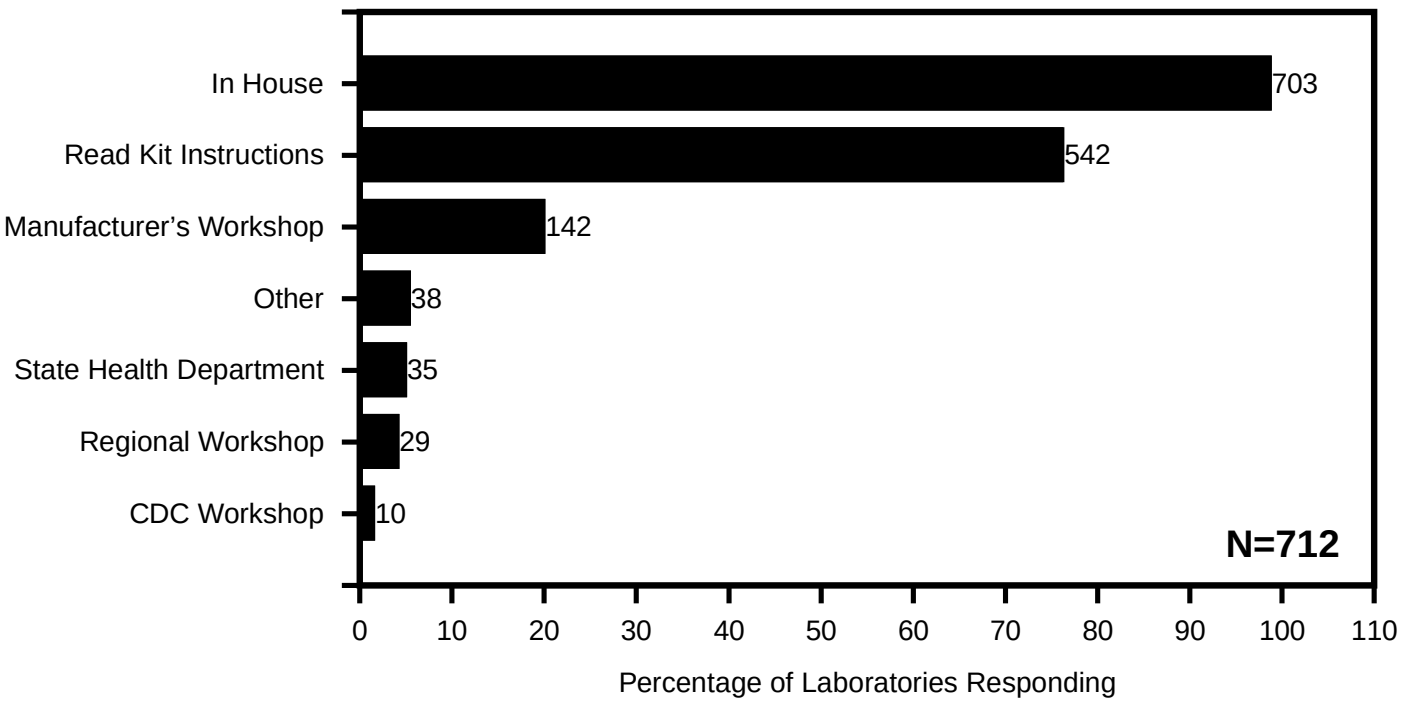


8.(a) Does your laboratory require testing personnel to have retroviral-specific training before they are considered qualified to perform tests?

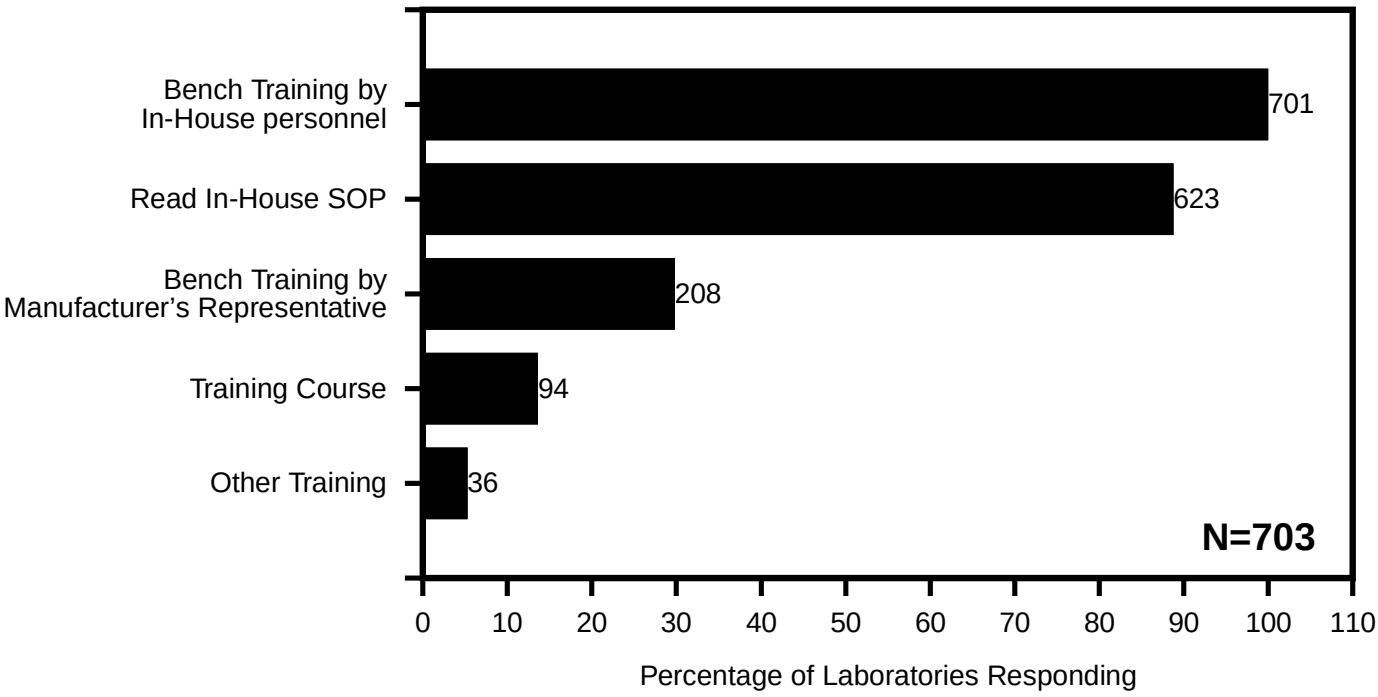


N=760

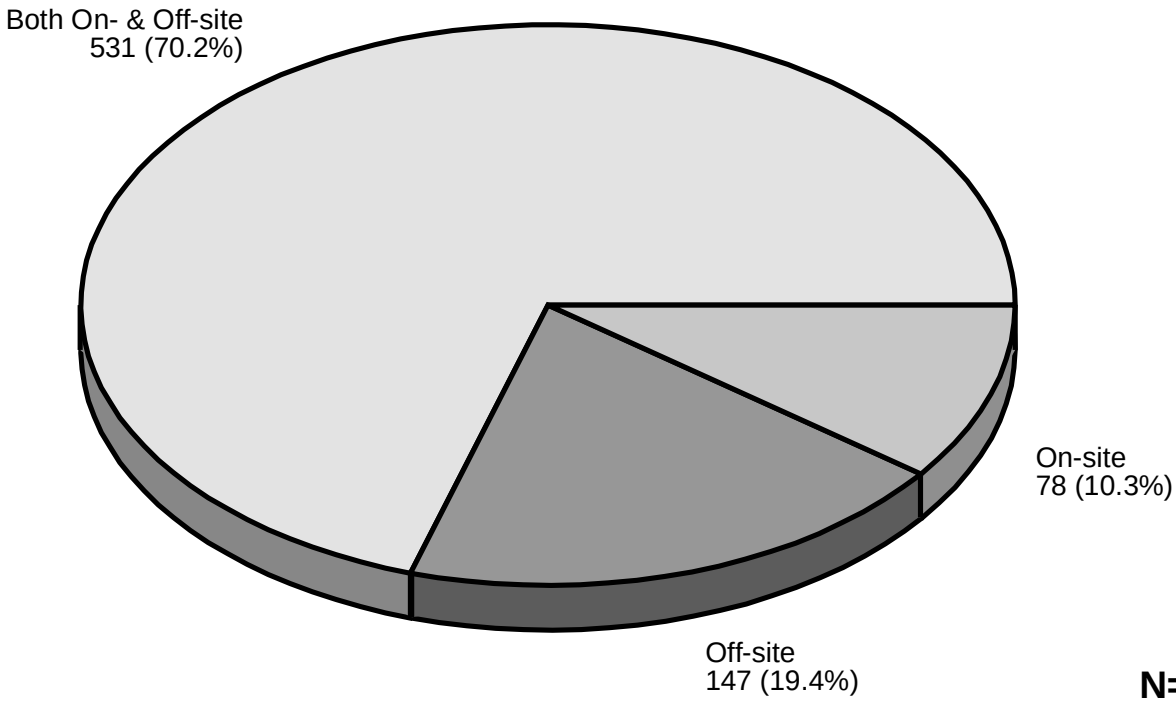
8.(b) If YES, what training must your personnel complete before they are considered qualified to perform retroviral testing? (Check all that apply.)



8.(c) If your personnel must complete in-house training before they are considered qualified to perform retroviral testing, indicate the type of in-house training (Check all that apply.):



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

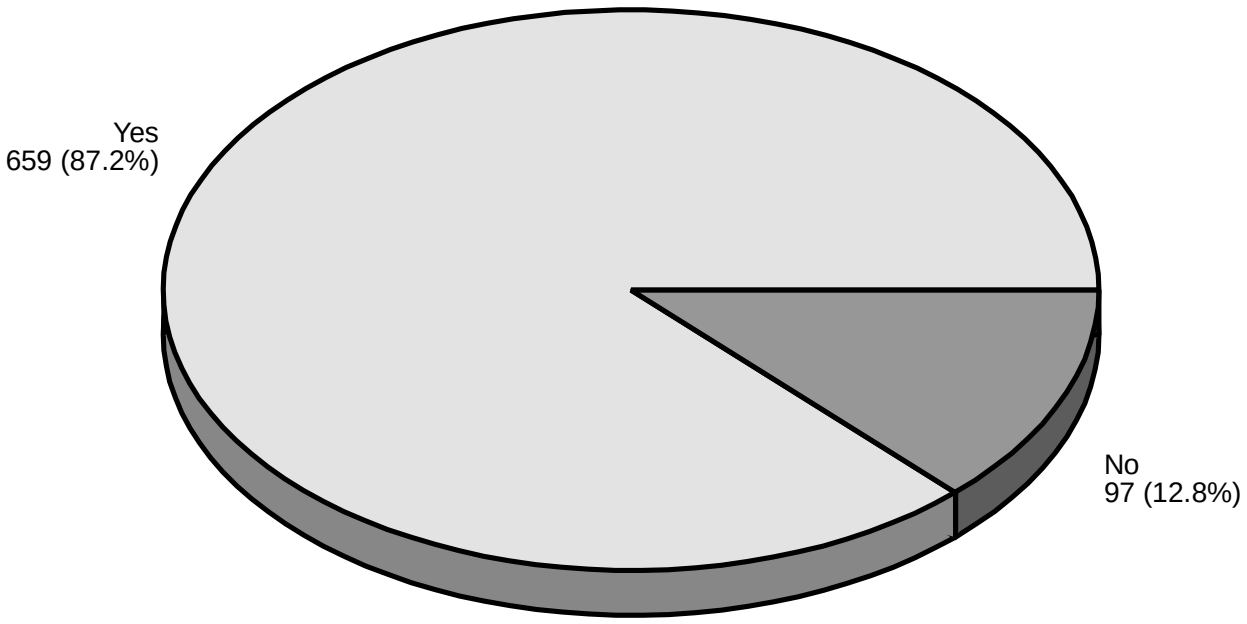


N=756

9.(b) Are written instructions provided for collecting, labeling, and transporting specimens?

Written Instructions	Collecting	Labeling	Transporting
No	16 (2.2%)	13 (1.8%)	40 (5.4%)
Yes	723 (97.8%)	727 (98.2%)	695 (94.6%)
Totals	739 (100.0%)	740 (100.0%)	735 (100.0%)

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

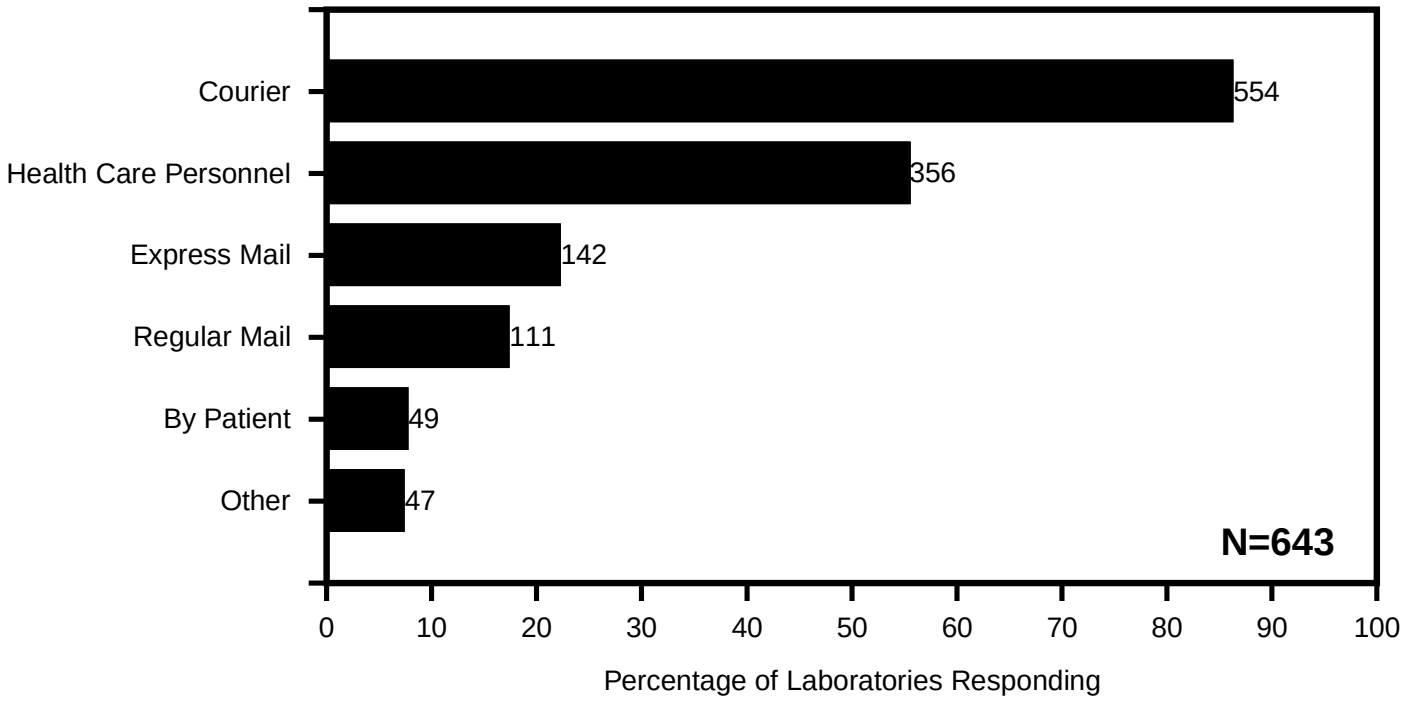


N=756

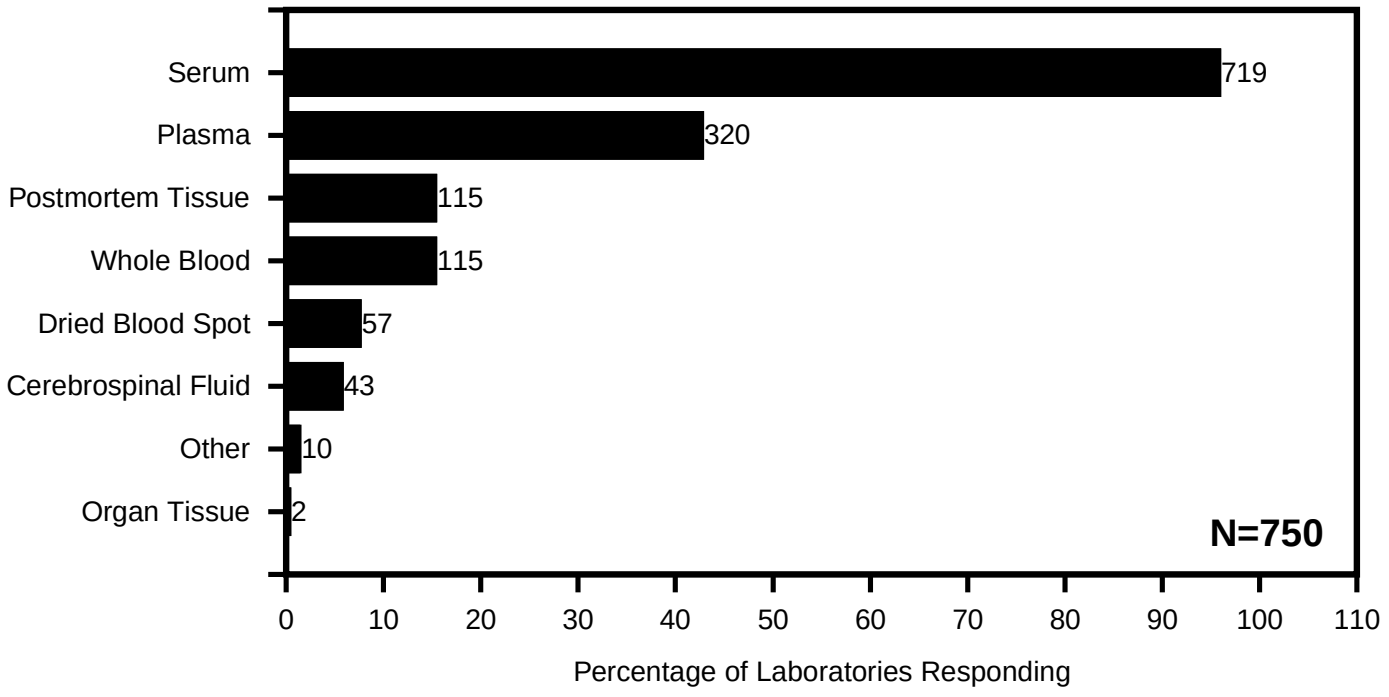
10.(b) If you test specimens collected off-site, please indicate where they are collected (Check all that apply.):

N=653 Collection Location	Number of Laboratories	Percentage of Laboratories		Collection Location	Number of Laboratories	Percentage of Laboratories
Private Physician	405	62.0		Medical Examiner/ Coroner's Office	148	22.7
Hospital	392	60.0		HMO	127	19.4
Outpatient Health Clinic	375	57.4		Out of State	112	17.2
Correctional Facility	219	33.5		Organ Donation Center	106	16.2
Counseling and Testing Site	215	32.9		Tuberculosis (TB) clinic	103	15.8
STD Clinic	215	32.9		Military Installation	97	14.9
Family Planning Center	189	28.9		Other Collection Sites	93	14.2
Drug Abuse Treatment Center	188	28.8		Uncertain/Unknown	46	7.0
Blood/Plasma Center	183	28.0				

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



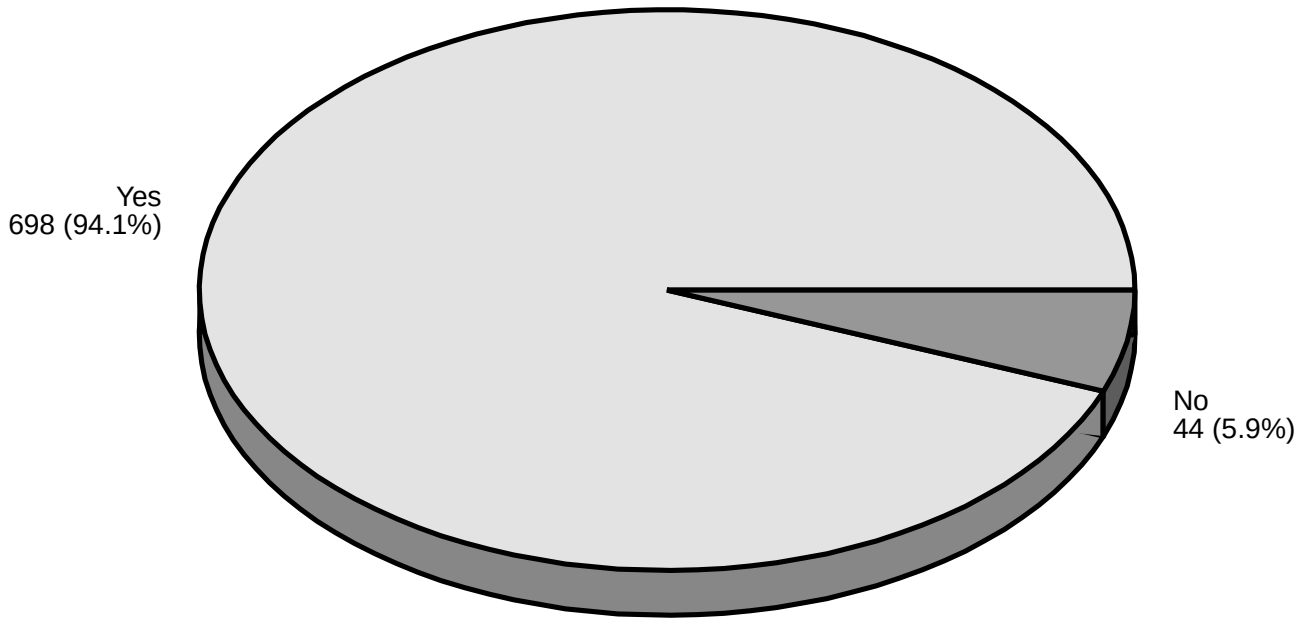
11. What types of specimens does your laboratory test for retroviral antibody? Please include all specimens tested (e.g., blood donor, diagnostic, serosurvey, neonatal dried blood spots, child-bearing women surveys). (Check all that apply.)



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

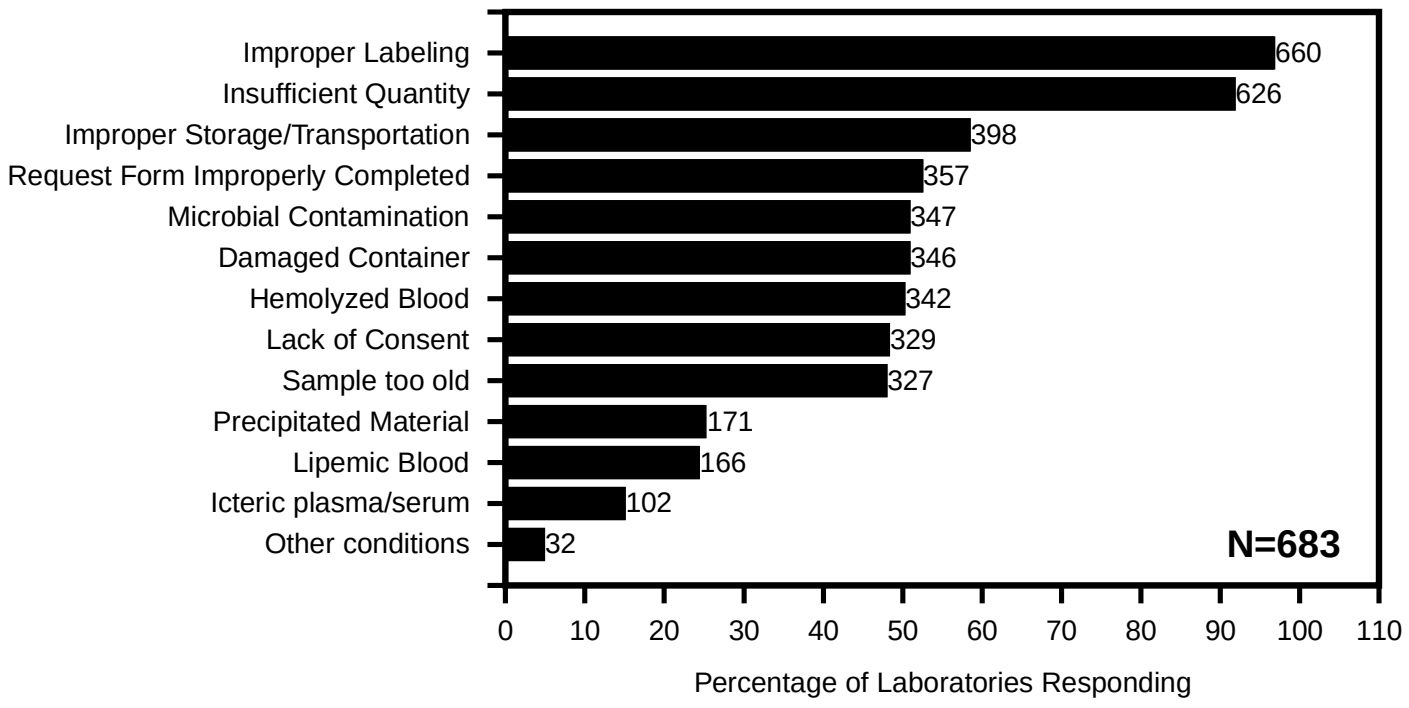
N=742 Type of Specimen	Heat Inactivation	Clarification by Centrifugation or filtration	No Pretreatment
Whole Blood	2	156	46
Plasma	11	127	216
Serum	17	254	465
Post Mortem	3	62	53
Dried Blood Spots	3	6	50
Organ Tissue	0	1	15
Cerebrospinal Fluid	3	9	37
Other	0	3	15

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

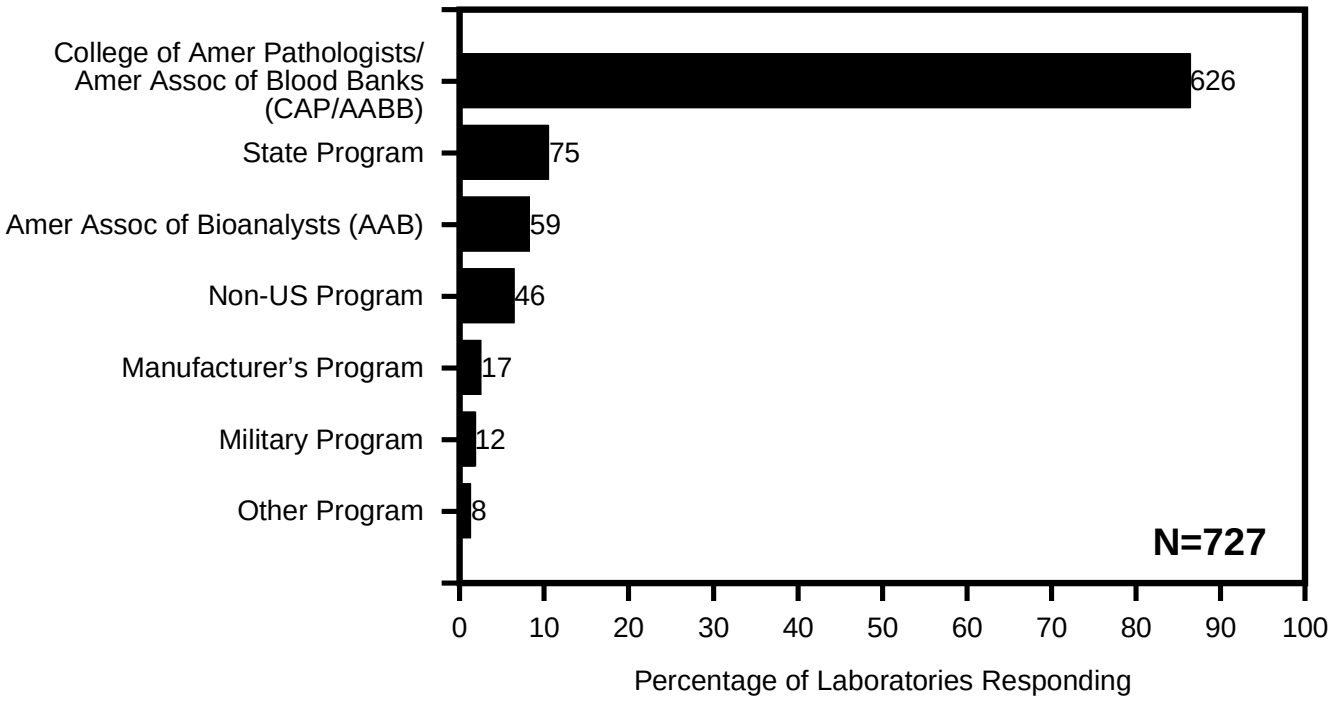


N=742

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) Indicate (1) the types of HIV-1 tests routinely performed in your labotatory, (2) the order in which they are performed (1st step, 2nd step, etc.), (3) whether an enzyme immunoassay (EIA) is performed singly or in duplicate, and (4) whether the EIA method used is manual or nonmanual:

N=458	Step 1	Step 2	Step 3	Step 4	Step 5	Number of Laboratories	Percentage of Laboratories
Algorithm*	EIA-S**	EIA-D**	A			124	27.1
	EIA-S	EIA-D	WB			94	20.5
	EIA-S	EIA-D	WB	A		30	6.6
	EIA-S	EIA-D				22	4.8
	EIA-S	A				11	2.4
	EIA-S	EIA-S	A			10	2.2
	EIA-S	EIA-D	IIF	A		8	1.7
	EIA-S	EIA-S	WB			8	1.7
	EIA-S	EIA-D	WB	O		7	1.5
	EIA-D	WB				6	1.3
	EIA-S	EIA-D	WB	IIF		5	1.1
	EIA-S	EIA-D	IIF	WB	A	5	1.1
Other Algorithms						128	27.9

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 107 unique algorithms were reported

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

15.(b) Indicate (1) the type(s) of HIV-1/HIV-2 tests routinely performed in your laboratory, (2) the order in which they are performed (1st step, 2nd step, etc.) (3) whether an enzyme immunoassay (EIA) is performed singly or in duplicate, and (4) whether the EIA method used is manual or nonmanual:

N=413	Step 1	Step 2	Step 3	Step 4	Step 5	Number of Laboratories	Percentage of Laboratories
Algorithm*	EIA 1/2-S**	EIA 1/2-D**	A			161	39.0
	EIA 1/2-S	EIA 1/2-D	WB-1			63	15.3
	EIA 1/2-S	EIA 1/2-D				34	8.2
	EIA 1/2-S	EIA 1/2-D	WB-1	EIA2-S	EIA2-D	9	2.2
	EIA 1/2-S	EIA 1/2-D	IIF			8	1.9
	EIA 1/2-S	EIA 1/2-D	WB-1	WB-2		7	1.7
	EIA 1/2-S	EIA 1/2-D	A			6	1.5
	EIA 1/2-S	EIA 1/2-D	WB-1	A		6	1.5
	EIA 1/2-S	EIA 1/2-S	A			5	1.2
Other Algorithms						114	27.6

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 98 unique algorithms were reported

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

16. Please indicate the number of months your laboratory has been performing these specific HIV tests:

N=703 Number of Months	EIA	WB	IIF	PCR	PA	HIV-1 Antigen	Viral Culture	Other
<=12	104	46	10	20	6	16	9	11
>12-24	26	15	8	14	3	11	3	4
>24-36	30	13	8	7	1	6	2	4
>36-48	24	7	1	7	1	6	1	2
>48-60	44	17	1	3	0	11	2	1
>60-72	29	7	3	1	0	5	2	0
>72-84	33	20	3	1	2	9	3	3
>84-96	50	31	5	1	2	12	5	0
>96-108	47	19	6	2	0	8	3	1
>108-120	115	36	11	0	1	6	4	2
>120-132	116	15	2	0	0	0	0	0
>132	74	7	0	0	1	1	1	3

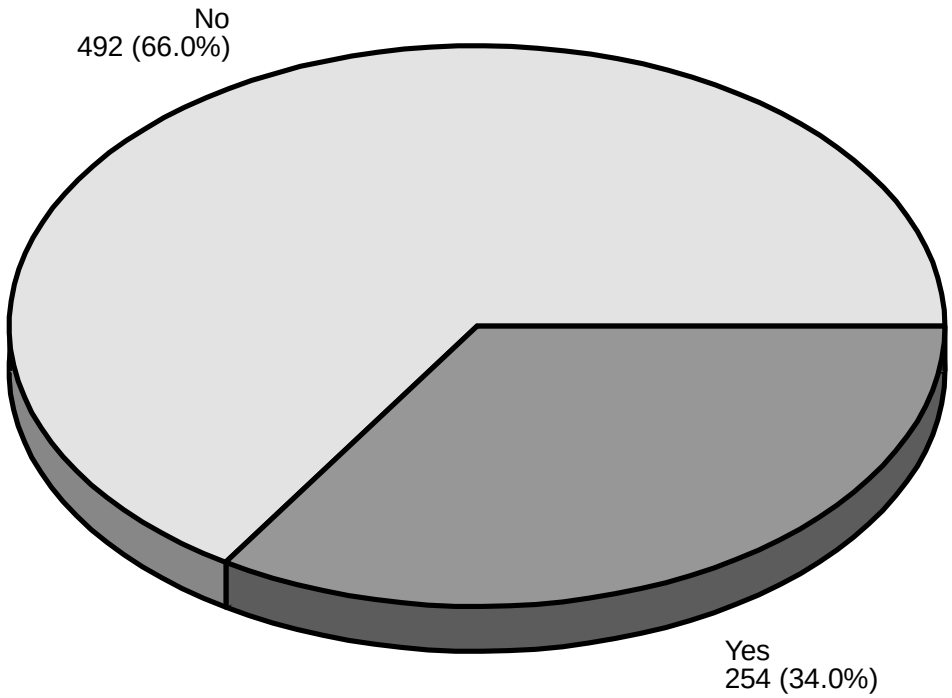
16. Please indicate the number of different employees in your laboratory that perform these specific HIV tests:

N=727 Number of Employees	EIA	WB	IIF	PCR	PA	HIV-1 Antigen	Viral Culture	Other
1	17	15	7	10	3	9	3	6
>1-4	293	143	32	42	8	51	23	16
>4-10	314	60	18	7	8	29	8	9
>10	91	18	1	0	1	8	1	2

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=751 Type of procedure	EIA	WB	IIF	Other
No written procedures	1	4	4	1
In-house written protocol	602	197	45	41
Manufacturers insert	651	213	39	45
Provided by State Health Department	50	13	8	1
Other sources	25	5	1	3

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



N=746

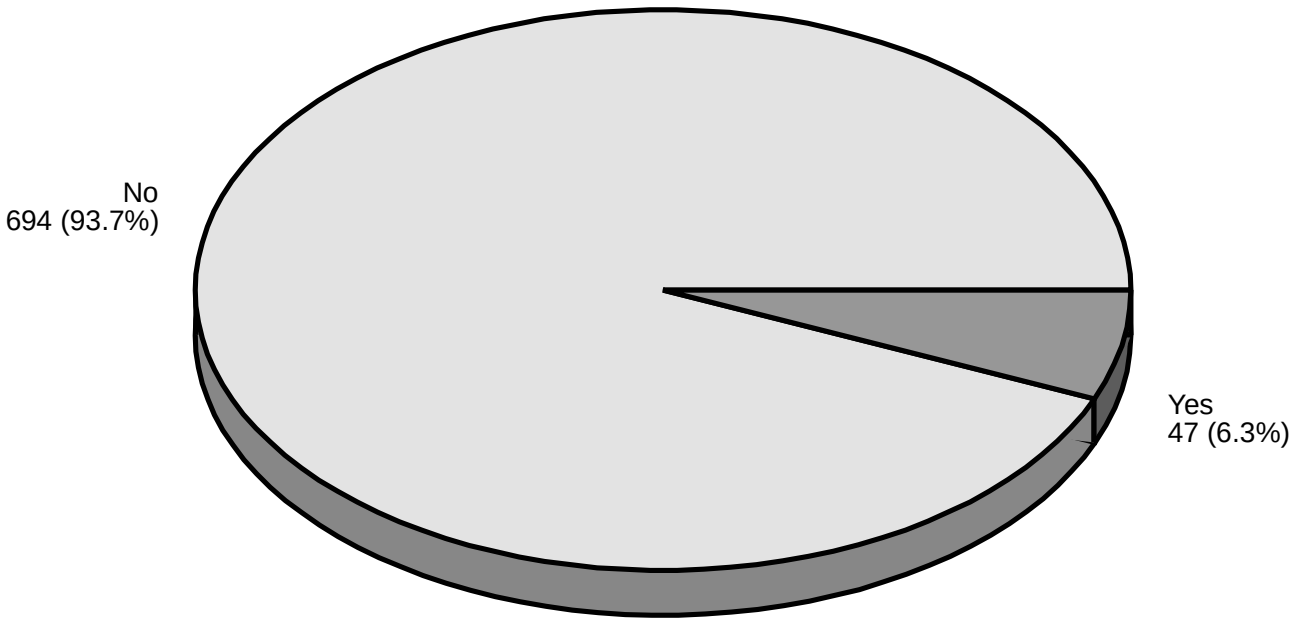
18.(b) Which of the following WB band patterns does your laboratory routinely use to classify a specimen as HIV-1 antibody reactive? (Check only one.)

N=251 Band Patterns	Number of Laboratories	Percentage of Laboratories
Any two of p24, gp41, gp120/gp160	215	85.7
Other	13	5.2
One protein from each: gag(p17/18, p24, p55), and env (gp41, gp120, gp160), and pol (p31, p51, p65/66)	8	3.2
p24 or p31, and gp41 or gp120/gp160	7	2.8
Two env bands w/ or w/o gag or pol bands	6	2.4
p24 plus p31, & (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? (Check only one.)

N=249 Band Patterns	Number of Laboratories	Percentage of Laboratories
No bands present	175	70.3
No HIV-1 specific protein bands	71	28.5
Other	3	1.2

19.(a) Do you perform an HIV antibody test other than EIA, WB, IIF, or HIV antigen detection?



N=741

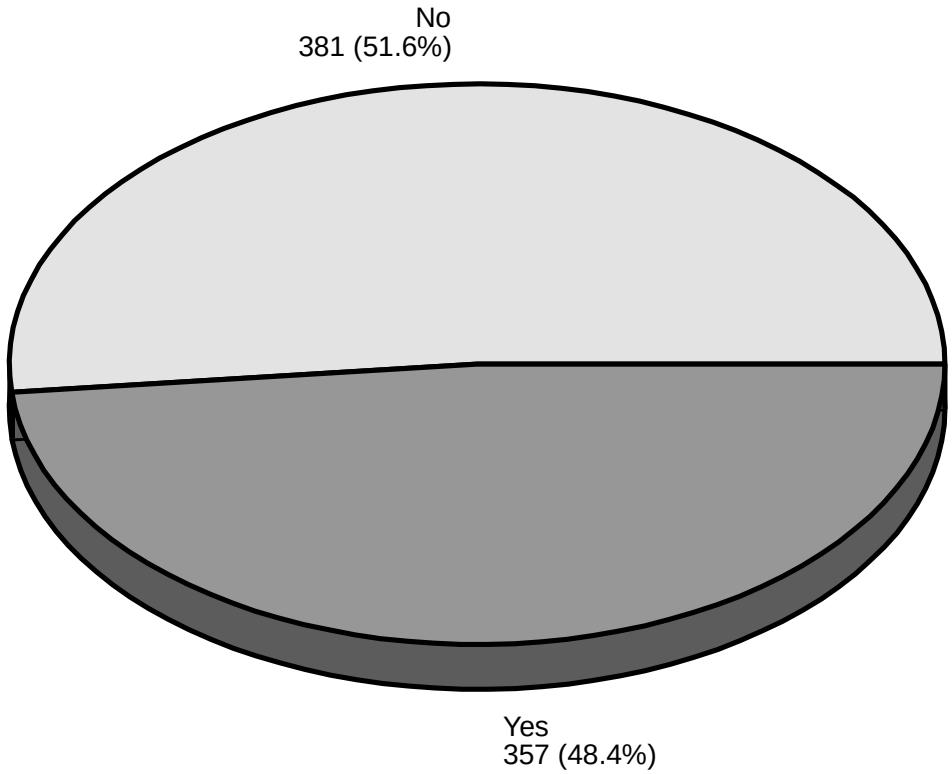
20. Please indicate the frequency with which your laboratory uses HIV control sera (other than kit manufacturer controls) for each of the test methods below (Check all that apply.):

N=453 Test Method	Each Test [a]	Each Set [b]	Two Each Day	Other Frequency
EIA	187	165	52	79
WB	7	121	9	25
IIF	10	25	3	3
Other	15	12	3	4

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

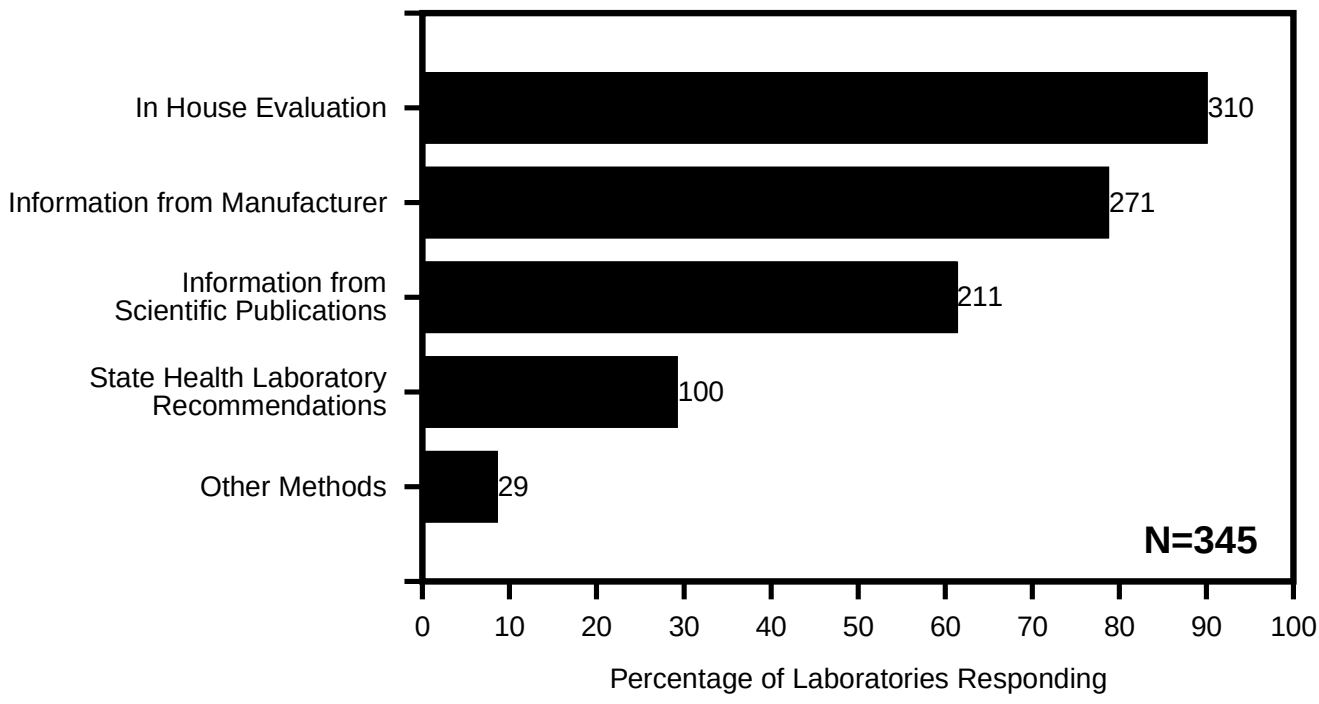
[b] A set of EIA plates, Western blot strips or IIF slides

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

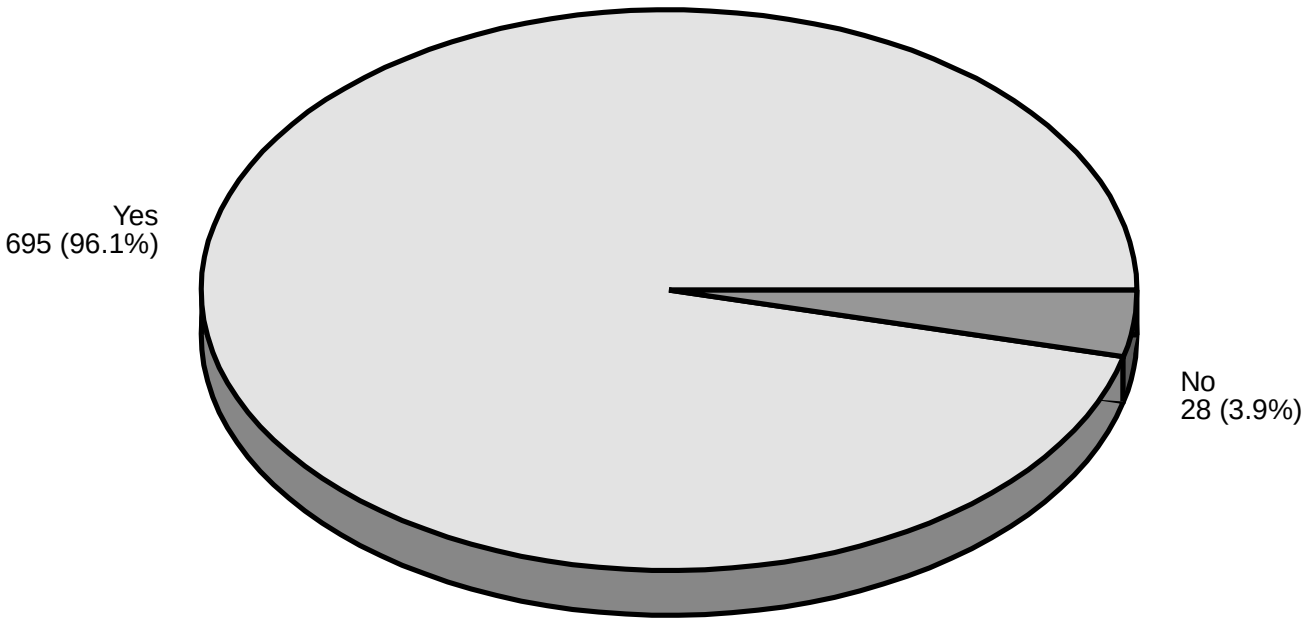


N=738

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

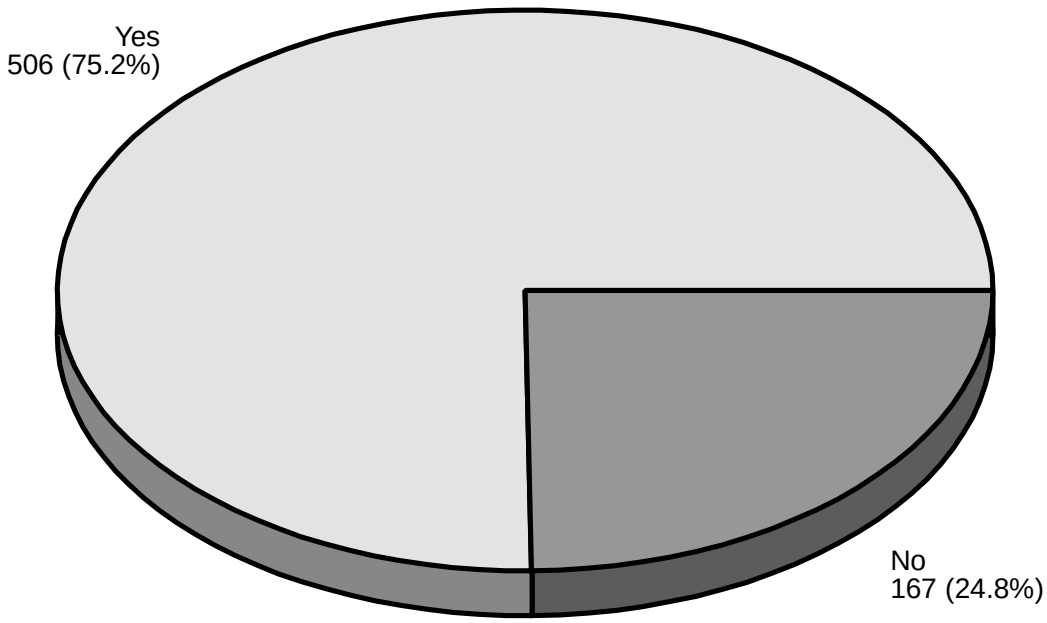


21.(c) Does your laboratory have a quality assurance plan?



N=723

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



N=673

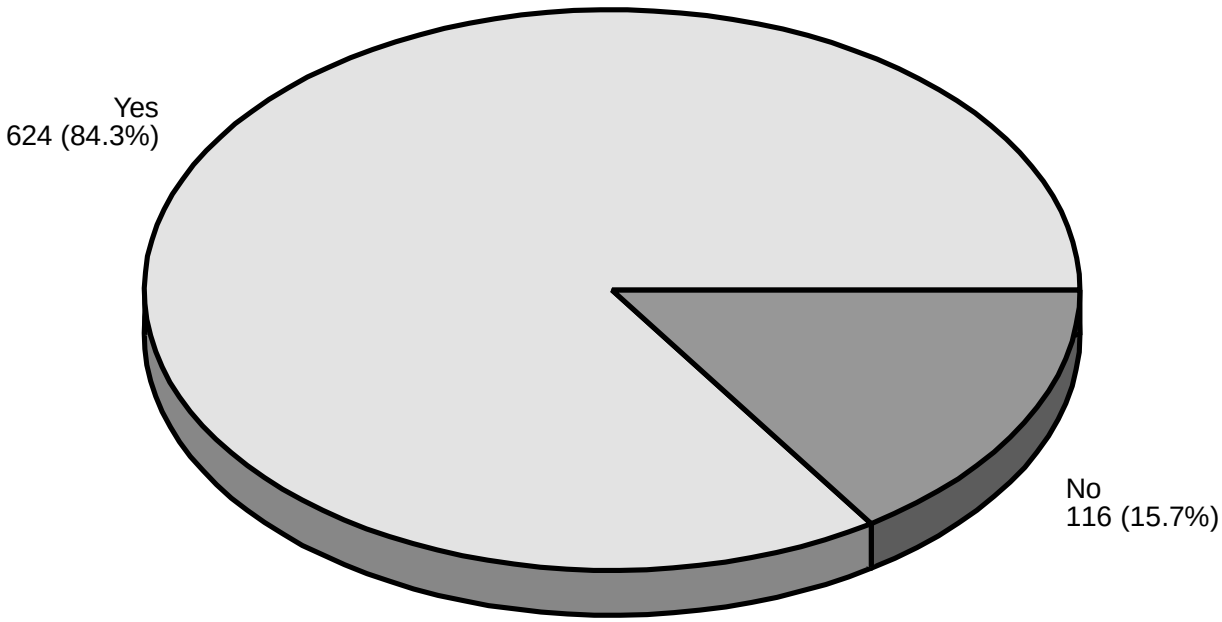
22. This question refers to the volume of HIV antibody testing performed in your laboratory. Responses should reflect the number of patient/donor specimens tested since your laboratory began testing (Round off to the nearest whole number.)

N=529 Number Since Testing Began	Total Specimens Tested	Reactive by Screen	Tested by Suppl/Conf	Reactive by Suppl/Conf
<10	1	39	34	52
10-99	3	92	79	84
100-999	26	156	138	133
1,000-9,999	136	117	105	74
10,000-99,999	210	31	32	26
100,000-999,999	124	2	4	3
1,000,000-9,999,999	18	1	1	0
>9,999,999	4	0	0	0

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 week. (Round off to the nearest whole number.)

N=693 Number During Most Recent Week	Total Specimens Tested	Reactive by Screen	Tested by Suppl/Conf	Reactive by Suppl/Conf
0	6	193	174	213
<10	38	311	265	235
10-99	291	112	113	84
100-999	269	8	11	6
1,000-9,999	89	0	0	0
10,000-99,999	4	0	0	0

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



N=740

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

N=613 Test Requested	Hospital	Health Department	Blood Bank	Independent	Other	Total
EIA HIV-1	4	51	9	57	33	154
EIA HIV-2	4	29	20	80	43	176
EIA HIV-1 HIV-2	10	9	10	50	21	100
WB HIV-1	26	90	32	261	72	481
WB HIV-2	14	30	16	172	68	300
IIF HIV-1	8	33	8	18	10	77
IIF HIV-2	2	10	1	14	5	32
PA	1	3	1	6	3	14
PCR	9	13	1	107	33	163
Culture	7	12	0	30	15	64
Antigen	12	5	2	88	27	134
Other	1	4	0	9	9	23

24. Indicate (1) the type(s) of HTLV tests routinely performed in your laboratory, (2) the order in which they are performed (1st step, 2nd step, etc.), (3) whether an enzyme immunoassay (EIA) is performed singly or in duplicate, and (4) whether the EIA method used is manual or nonmanual:

N=255	Step 1	Step 2	Step 3	Step 4	Number of Laboratories	Percentage of Laboratories
Algorithm*	EIA-S**	EIA-D**	A		123	48.2
	EIA-S	EIA-D			34	13.3
	EIA-S	EIA-D	WB		19	7.5
	EIA-S	EIA-D	WB	A	7	2.7
	EIA-S	EIA-D	WB	A	6	2.4
	EIA-S	EIA-D	A		5	2.0
	EIA-S	EIA-D	WB	O	4	1.6
	EIA-S	WB			4	1.6
	EIA-S	A			4	1.6
	WB				4	1.6
Other Algorithms					45	17.6

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 46 unique algorithms were reported

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

25. Please indicate the number of months your laboratory has been performing these specific HTLV-I/II tests:

N=227 Number of Months	EIA	WB	IIF	PCR	PA	RIPA	HTLV Antigen	Viral Culture	Other
<=12	30	7	0	6	1	1	0	0	2
>12-24	13	5	1	2	1	0	0	0	0
>24-36	16	4	1	0	0	0	0	0	1
>36-48	5	4	0	0	0	0	1	0	0
>48-60	22	3	0	2	0	1	1	0	0
>60-72	24	3	0	1	0	0	0	1	0
>72-84	71	6	0	1	0	0	0	0	0
>84-96	23	2	0	0	1	1	0	0	0
>96-108	3	2	1	0	0	0	0	0	0
>108	14	0	1	0	1	0	0	0	0

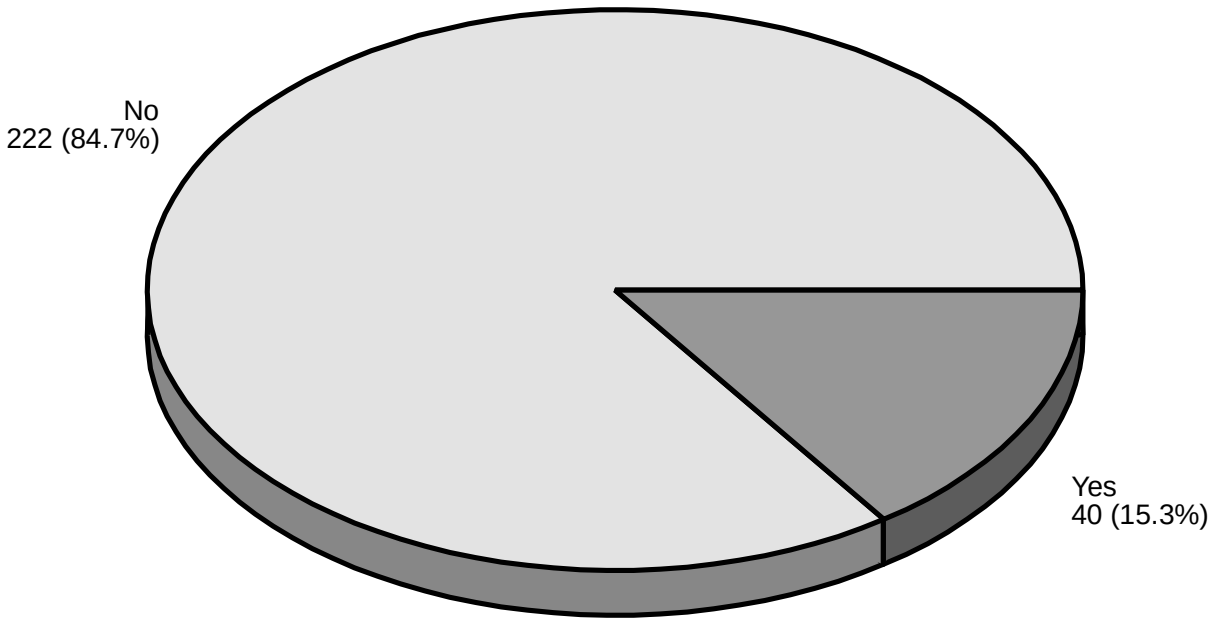
25. Please indicate the number of different employees in your laboratory that perform these specific HTLV-I/II tests:

N=242 Number of Employees	EIA	WB	IIF	PCR	PA	RIPA	HTLV Antigen	Viral Culture	Other
1	6	2	0	2	1	0	0	1	0
>1-4	79	24	5	7	3	2	2	0	2
>4-10	102	9	1	1	0	1	0	0	1
>10	48	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=255 Type of procedure	EIA	WB	IIF	Other
No written procedures	0	0	1	0
In-house written protocol	210	33	2	11
Manufacturers insert	221	30	1	6
Provided by State Health Department	6	0	0	0
Other sources	15	1	0	1

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



N=262

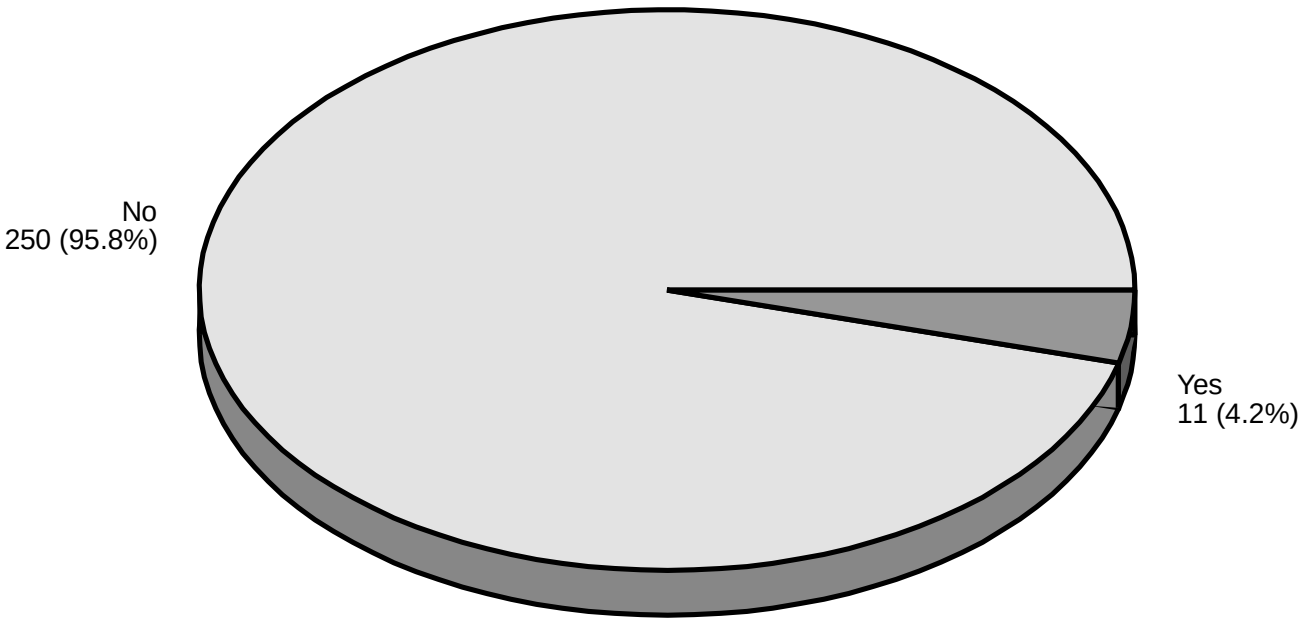
27.(b) Which of the following WB band patterns does your laboratory routinely use to classify a specimen as HTLV-I/II antibody reactive? (Check only one.)

N=40 Band Patterns	Number of Laboratories	Percentage of Laboratories
p24 and gp46 or r21e (recombinant envelope protein)	15	37.5
Other	9	22.5
p19 or p24, and gp46 or gp61/68	8	20.0
One protein from each of the viral gene product groups: gag(19, p24), and env (gp21, gp46, gp61/68)	4	10.0
any HTLV-I/II specific protein bands	2	5.0
p24 and gp46 or gp61/68	2	5.0

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

N=40 Band Patterns	Number of Laboratories	Percentage of Laboratories
No HTLV-I/II specific protein band(s)	22	55.0
No bands present	17	42.5
Other	1	2.5

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

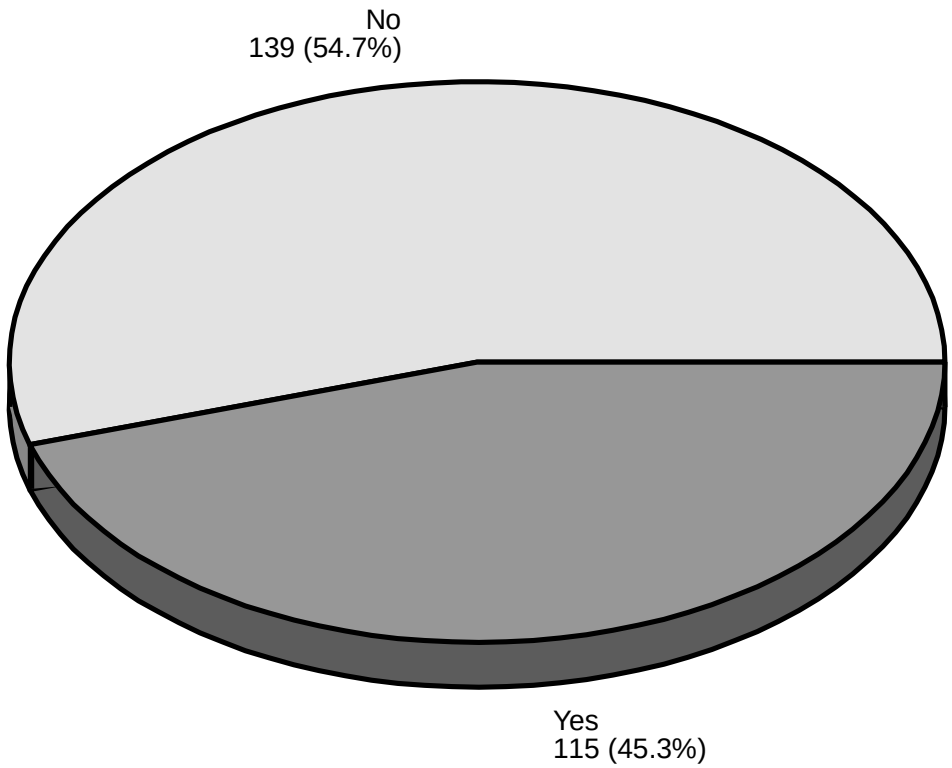


N=261

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

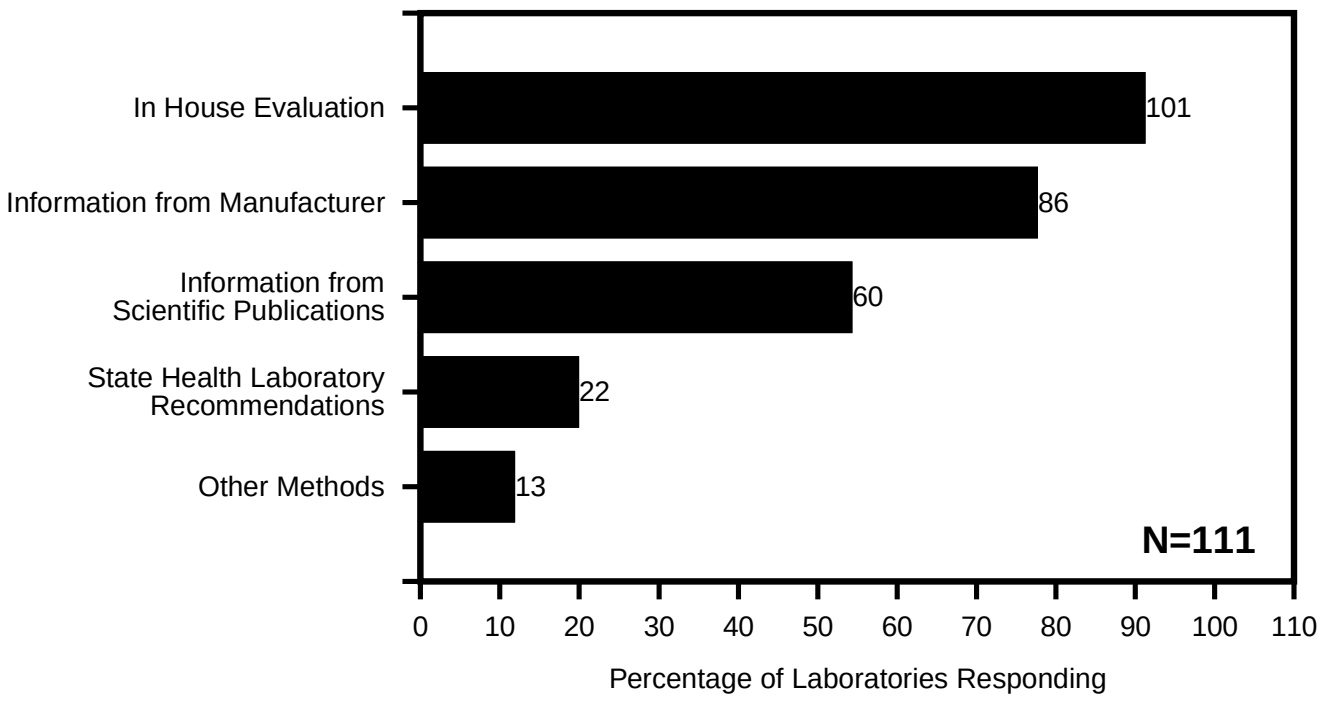
N=124 Test Method	Each Test	Each Set	Two Each Day	Other Frequency
EIA	49	41	7	25
WB	0	28	1	2
IIF	0	3	0	0
Other	3	5	2	1

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

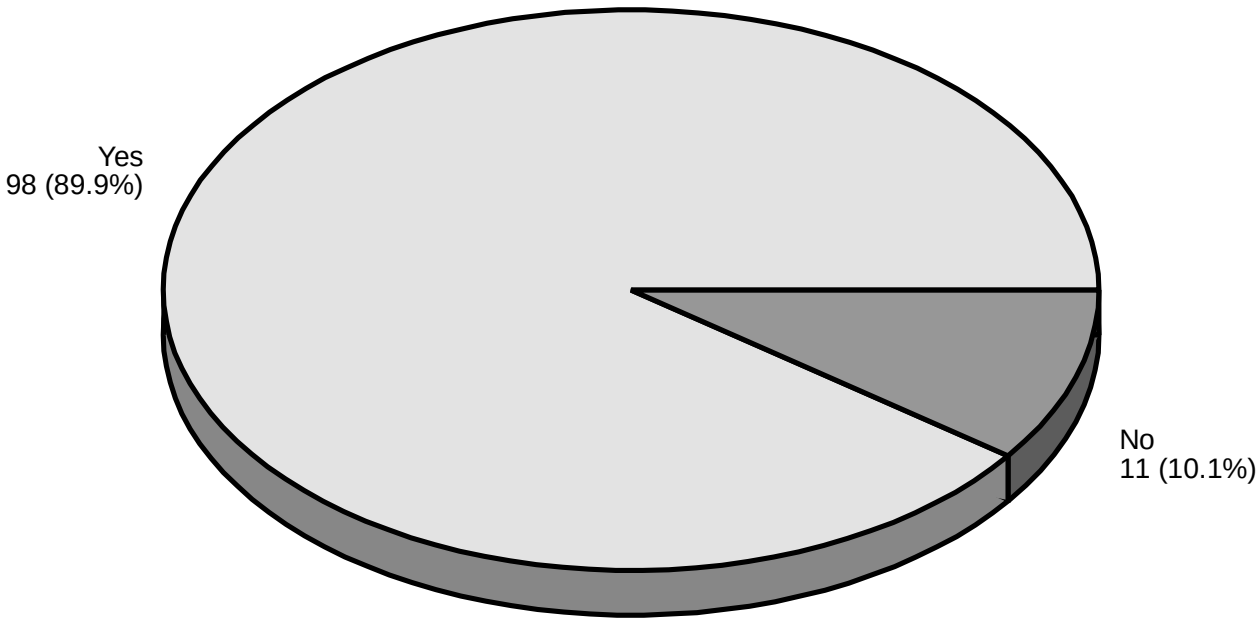


N=254

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

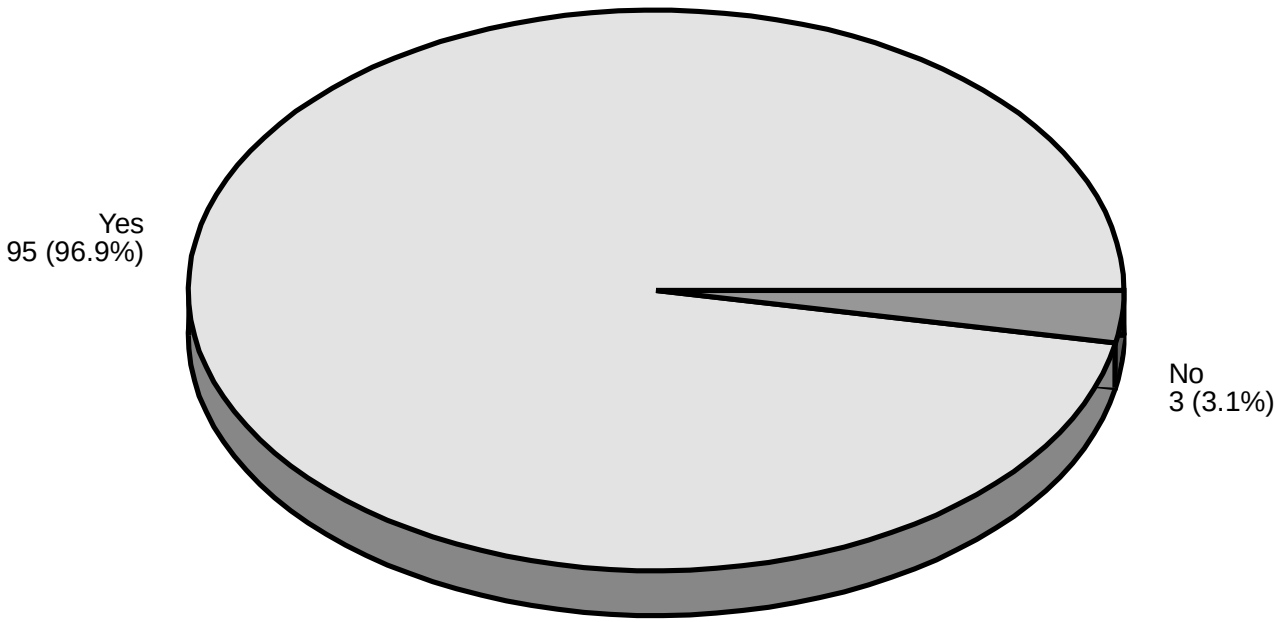


30.(c) Does your laboratory have an HTLV quality assurance plan?



N=109

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



N=98

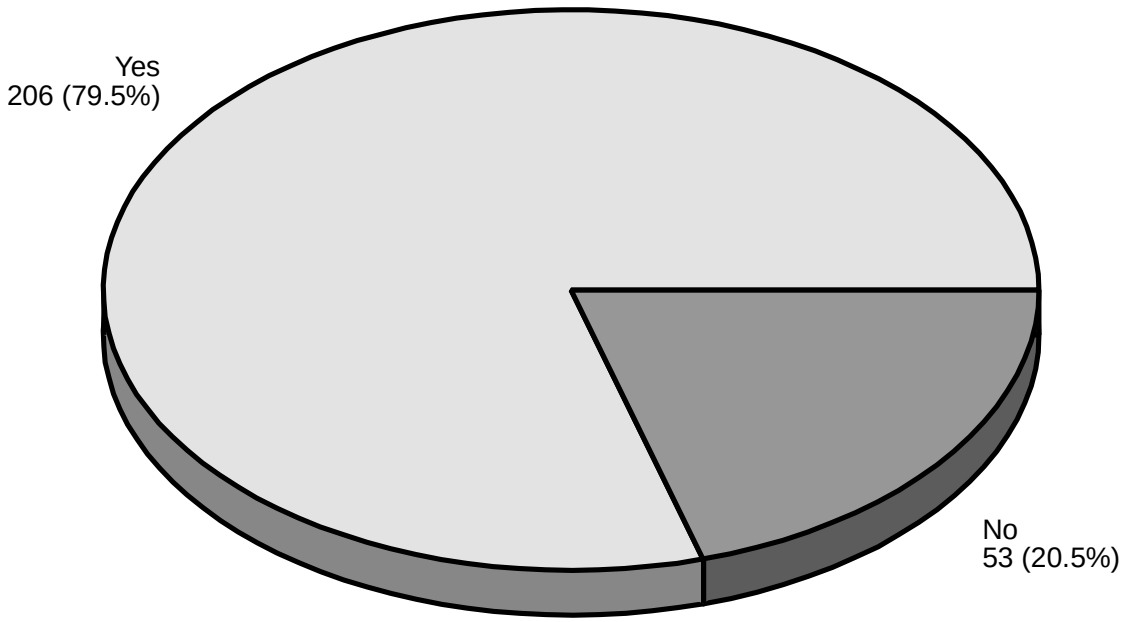
31. This question refers to the volume of HTLV-I/II antibody testing performed in your laboratory. Responses should reflect the number of patient/donor specimens tested since your laboratory began testing. (Round off to the nearest whole number.)

N=166 Number Since Testing Began	Total Specimens Tested	Reactive by Screen	Tested by Suppl/Conf	Reactive by Suppl/Conf
<10	0	35	27	51
10-99	5	42	41	29
100-999	16	39	32	10
1,000-9,999	45	13	13	5
10,000-99,999	53	1	3	0
100,000-999,999	41	0	0	0
1,000,000-9,999,999	3	0	0	0

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 week. (Round off to the nearest whole number.)

N=220 Number During Most Recent Week	Total Specimens Tested	Reactive by Screen	Tested by Suppl/Conf	Reactive by Suppl/Conf
0	6	103	91	124
<10	36	79	62	28
10-99	73	7	7	3
100-999	81	1	2	0
1,000-9,999	28	0	0	0
10,000-99,999	1	0	0	0

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



N=259

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

N=204 Test Requested	Hospital	Health Department	Blood Bank	Independent	Other	Total
EIA	1	5	4	20	19	49
WB	10	8	18	113	45	194
IIF	0	1	0	3	0	4
PA	0	0	0	0	2	2
RIPA	2	1	2	34	22	61
PCR	1	4	2	12	4	23
Culture	0	0	0	2	1	3
Antigen	0	1	1	2	0	4
Other	0	0	0	1	0	1