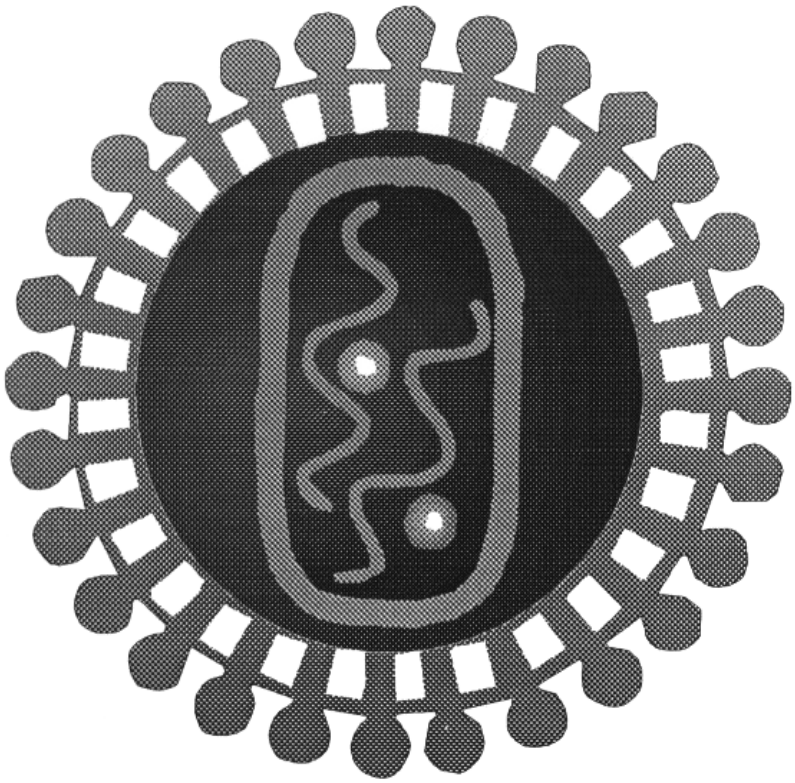
Results of the 2004 Retroviral Testing Survey Questionnaire Sent to Laboratories Participating in the Model Performance Evaluation Program



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

CENTERS FOR DISEASE CONTROL AND PREVENTION

This report provides the results of the **2004 Retroviral Laboratory Questionnaire Survey** mailed to laboratories participating in the Model Performance Evaluation Program, Centers for Disease Control and Prevention (CDC).

Purpose

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 and HIV-1 ribonucleic acid.

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Introductory Comments on the Model Performance Evaluation Program 2004 Retroviral Questionnaire Survey Results

The Model Performance Evaluation Program (MPEP) retroviral questionnaire survey was mailed March 26, 2004 to 892 laboratories;

Of the 892 laboratories receiving the questionnaire;

- 660 were laboratories located in the United States (U.S.) or in U.S. territories, 518 (78.5%) returned completed surveys,
- 232 laboratories were located outside the U.S., 96 (41.4%) returned completed surveys,
- 15 laboratories refused the survey,
- 20 disenrolled,
- 851 agreed to complete the survey, and
- 614 laboratories actually returned the completed survey.

The overall response rate was 72.2% (614/851).

Aggregate data are presented in the following report.

Numbers and values used in the graphics

The "N =" and numbers appearing on each chart 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.

The following terms and abbreviations were used in this survey:

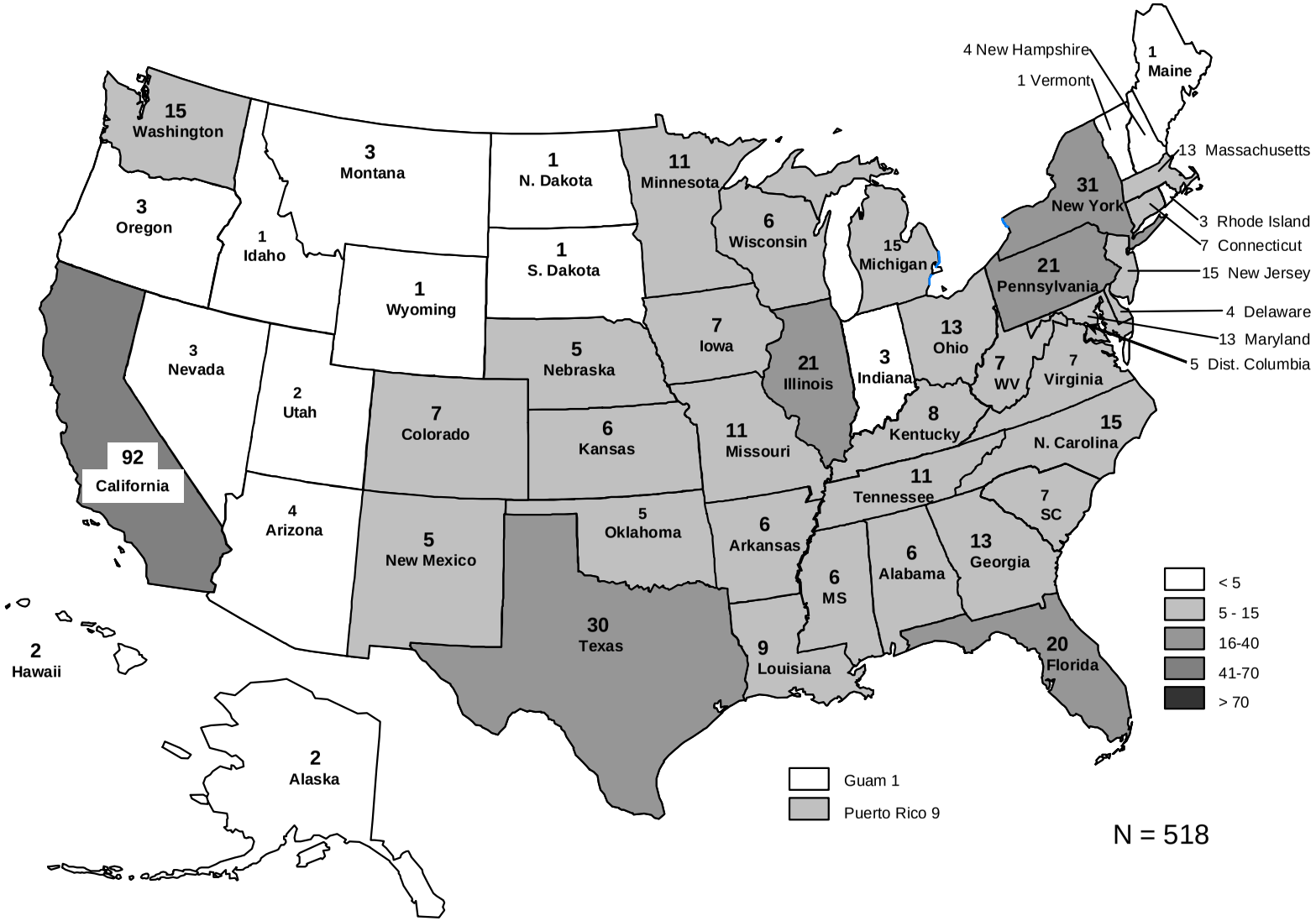
Ab	Antibody
HIV	Human immunodeficiency virus (type 1 or type 2)
HMO	Health Maintenance Organization
EIA	Enzyme immunoassay, also called ELISA (enzyme-linked immunosorbent assay)
WB	Western blot
IFA	Indirect fluorescent antibody (IFA), also called indirect immunofluorescence (IIF)
PA	Particle agglutination
p24 Ag	p24 antigen
PCR	Polymerase chain reaction: a gene amplification technique
PPO	Preferred Provider Organization
RNA	Ribonucleic acid
DNA	Deoxyribonucleic acid
On-Site Collection	Samples drawn by the testing laboratory or the associated institution
Off-Site Collection	Samples drawn outside of the testing laboratory or the associated institution
Most Recent Representative Month	A 28-31 day period in which a typical number of HIV specimens are tested

The Number of Laboratories Participating in the Retroviral Survey by Country

N =614

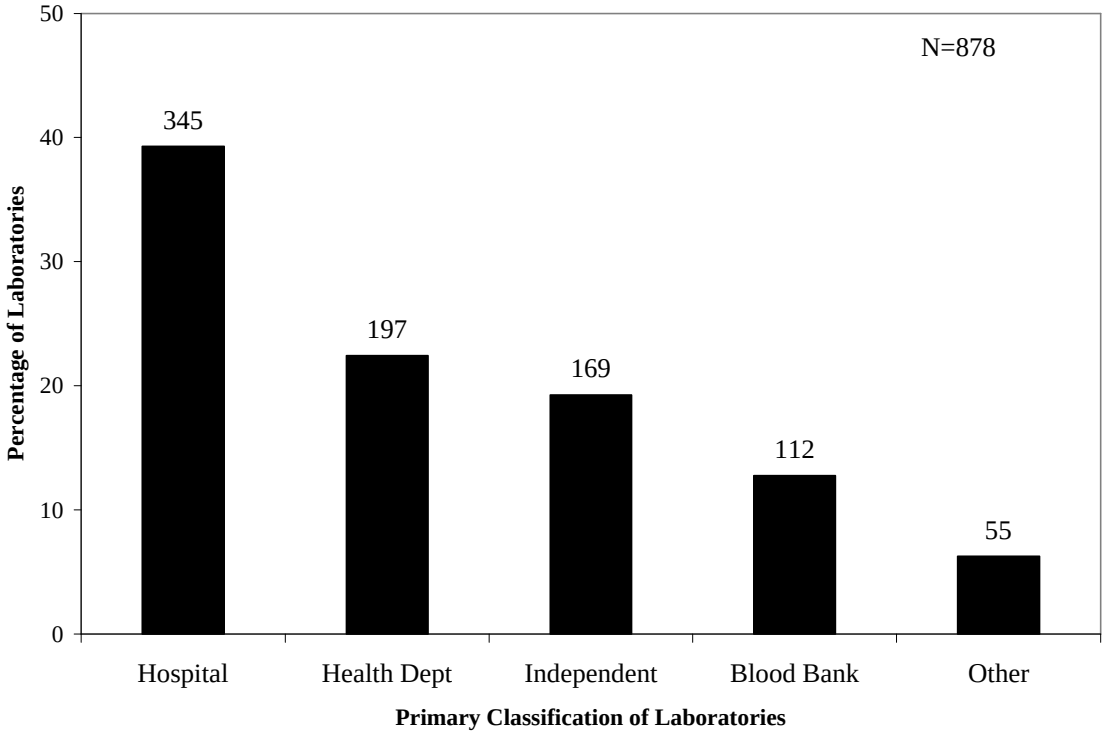
Country	Number of Laboratories	Country	Number of Laboratories	Country	Number of Laboratories
Algeria	1	Honduras	1	South Africa	1
Argentina	3	Hong Kong	2	Spain	1
Australia	5	Hungary	1	Sri Lanka	3
Austria	3	India	3	Switzerland	1
Bahamas	1	Israel	3	Taiwan	1
Belgium	2	Japan	1	Tanzania	1
Brazil	2	Kazakhstan	1	Thailand	3
Canada	16	Kyrgyzstan	2	Trinidad	1
Costa Rica	2	Malaysia	1	Turkmenistan	1
Croatia	1	Malta	1	US Territory	10
Denmark	3	Myanmar (Burma)	1	Uganda, East Africa	1
Dominican Republic	2	Peru	2	United States	508
Ecuador	1	Philippines	1	Uruguay	1
El Salvador	1	Portugal	1	Venezuela	2
England	1	Republic of Singapore	1	Vietnam	1
Eritrea	1	Saudi Arabia	2	Zambia	1
Germany	1	Slovakia	1	Zimbabwe	2
Ghana	2	Slovenia (Yugoslavia)	2		

Number of U.S. MPEP Laboratories Participating in the Retroviral Survey

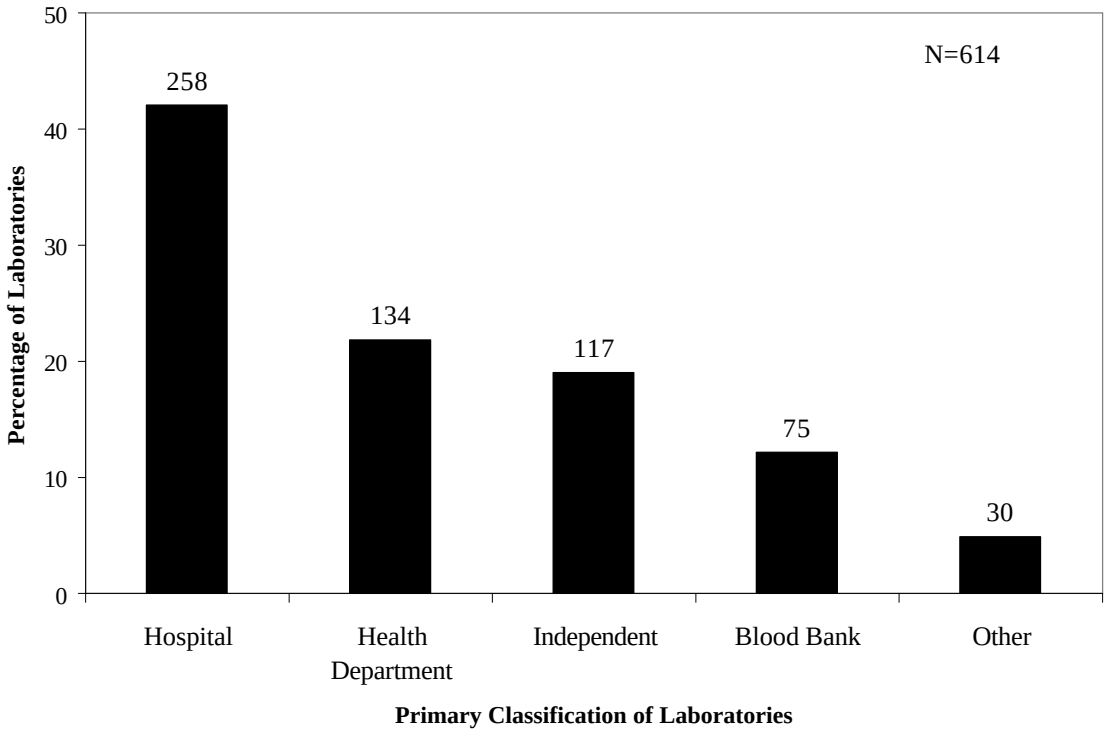


The next two charts show primary classifications of MPEP laboratories enrolled in the retroviral program obtained from the demographic information entered by the laboratory.

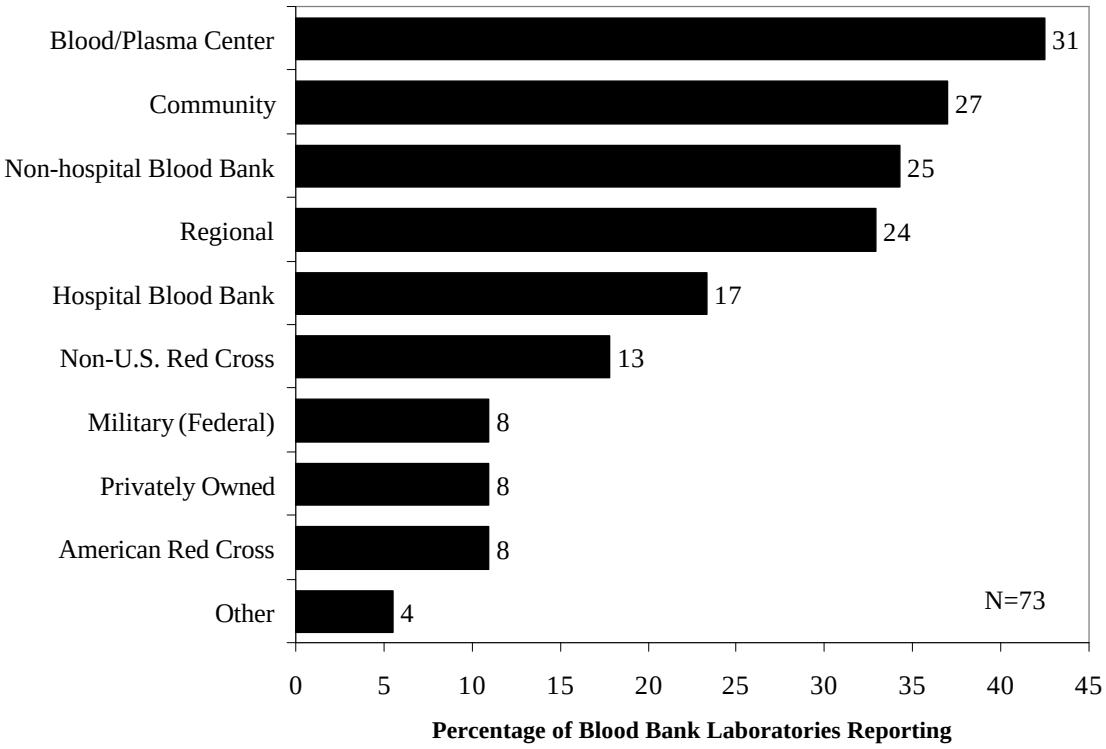
Total Laboratories Enrolled in the MPEP by Laboratory Type



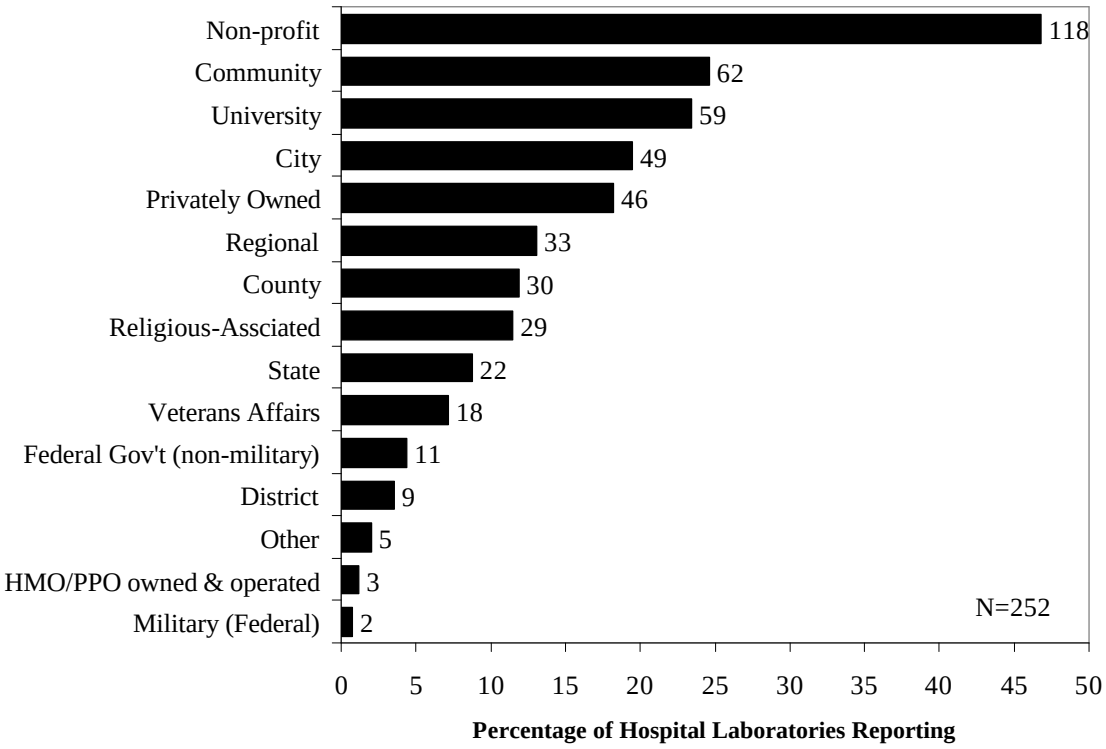
Classification of Laboratories Responding to Questionnaire Survey



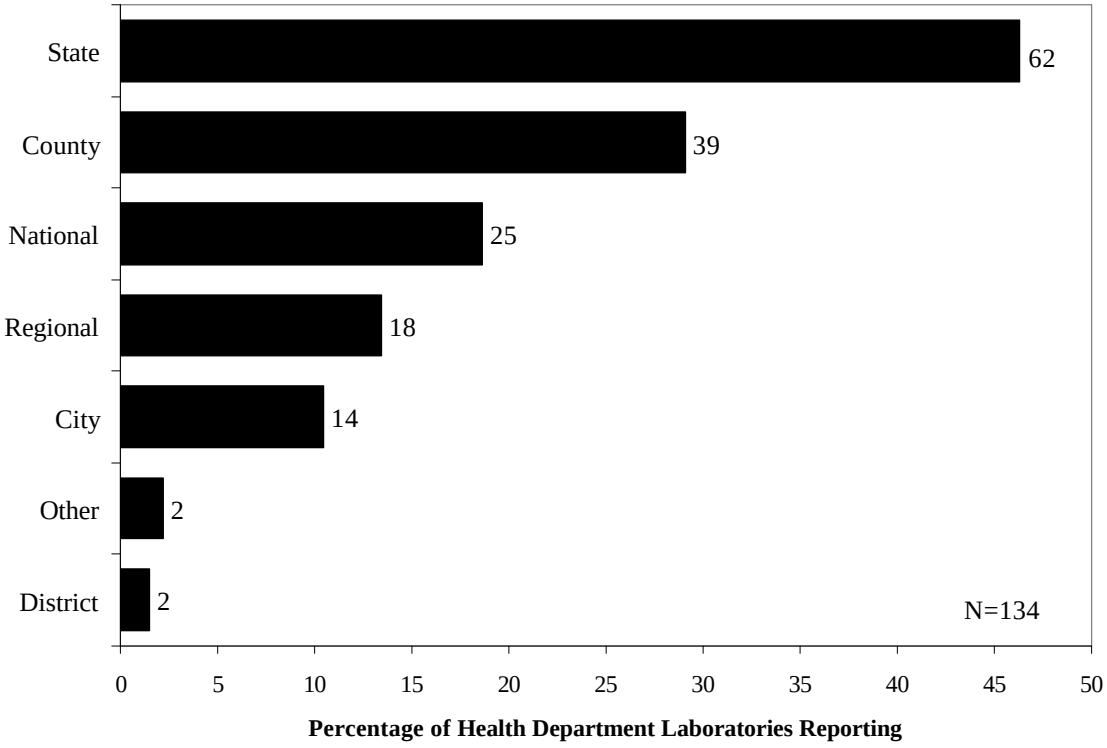
3. (a) If the laboratory type shown on your mailing label (located on page one) is BLOOD BANK, please further describe your HIV testing laboratory. (Check <u>all</u> that apply within your Blood Bank laboratory classification.)



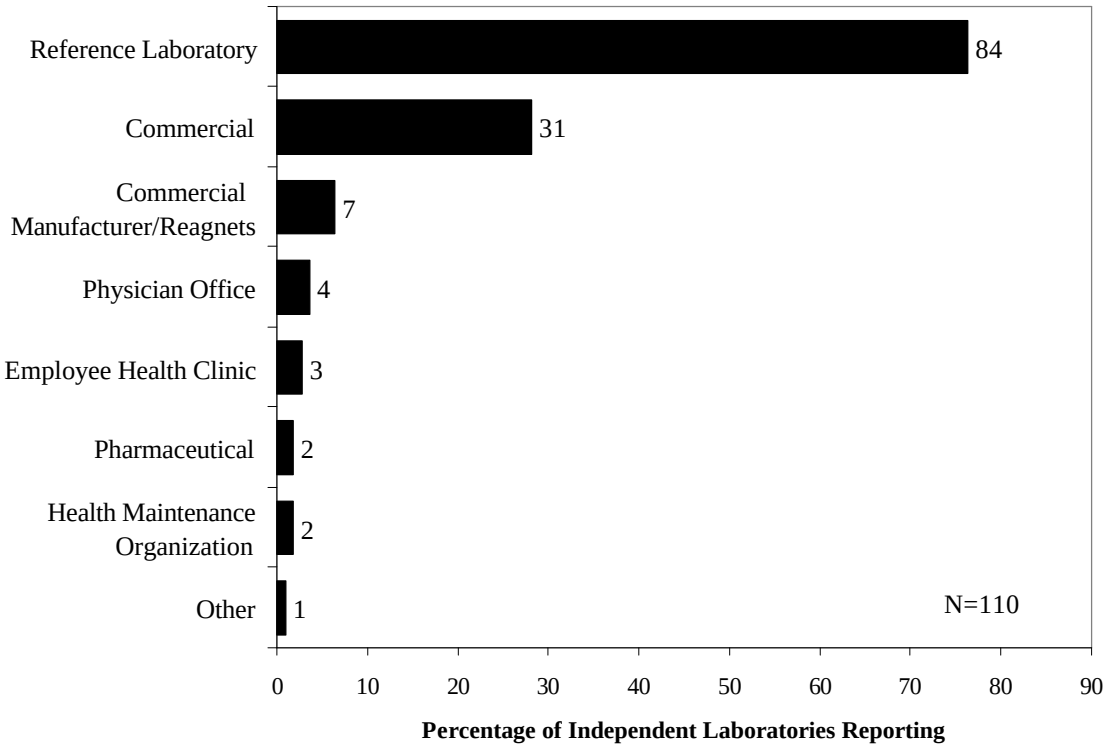
3. (b) If the laboratory type shown on your mailing label (located on page one) is HOSPITAL, please further describe your HIV testing laboratory. (Check all that apply within your Hospital laboratory classification.)



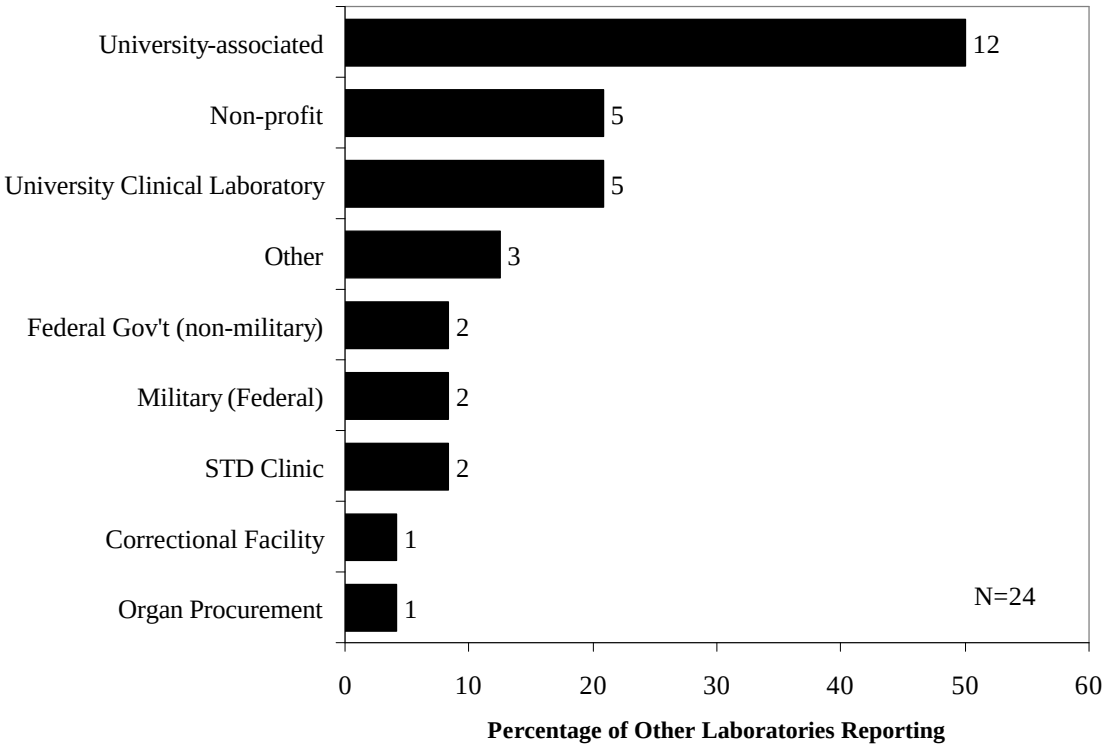
3. (c) If the laboratory type shown on your mailing label (located on page one) is HEALTH DEPARTMENT (or Government Health System as indicated in some countries outside the United States), please <u>further describe</u> your HIV testing laboratory. (Check <u>all</u> that apply within your Health Department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



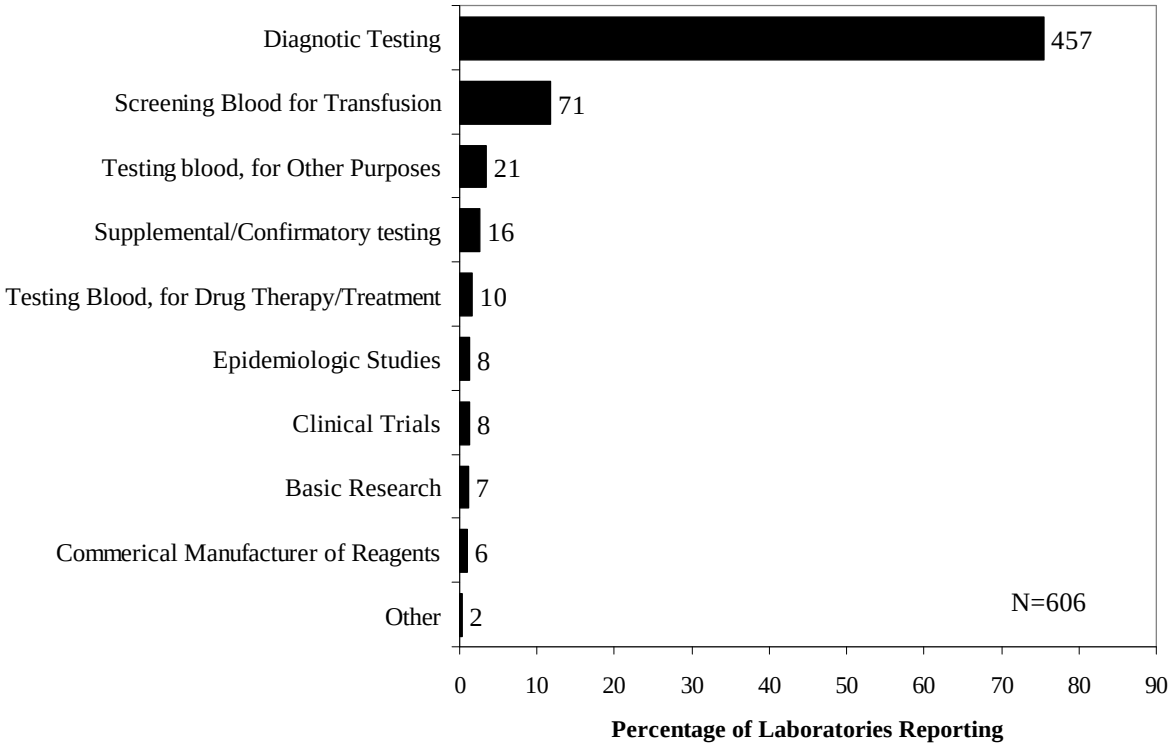
3. (d) If the laboratory type shown on your mailing label (located on page one) is INDEPENDENT, please <u>further describe</u> your HIV testing laboratory. (Check <u>all</u> that apply within your Independent laboratory classification.)



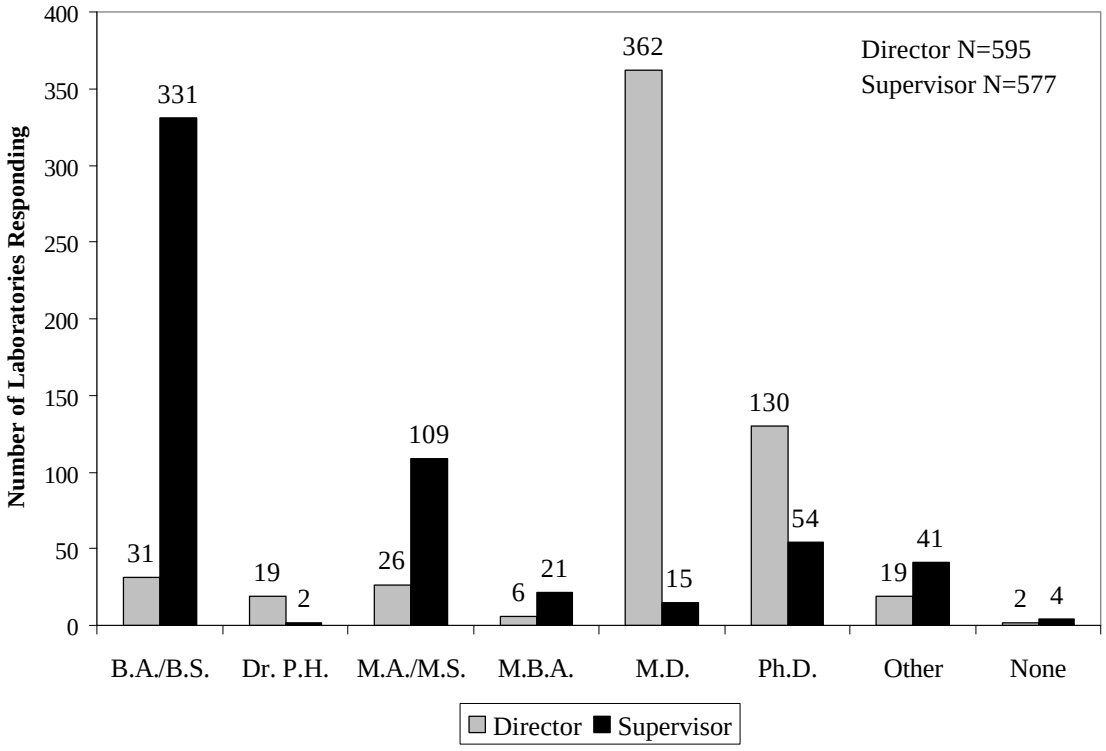
3. (e) If the laboratory type shown on your mailing label (located on page one) is OTHER, please <u>further describe</u> your HIV testing laboratory. (Check <u>all</u> that apply within your Other laboratory classification.)



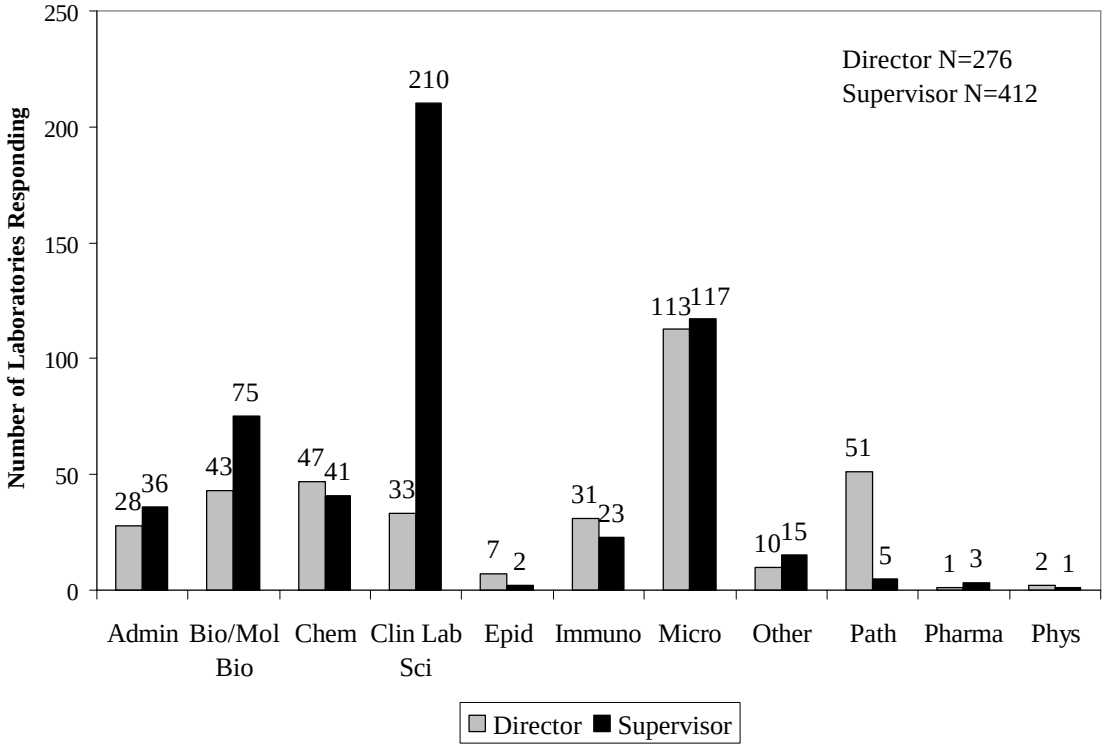
4. What is the *<u>primary purpose</u>*** of your HIV testing operation? (Choose only <u>one</u>.)**



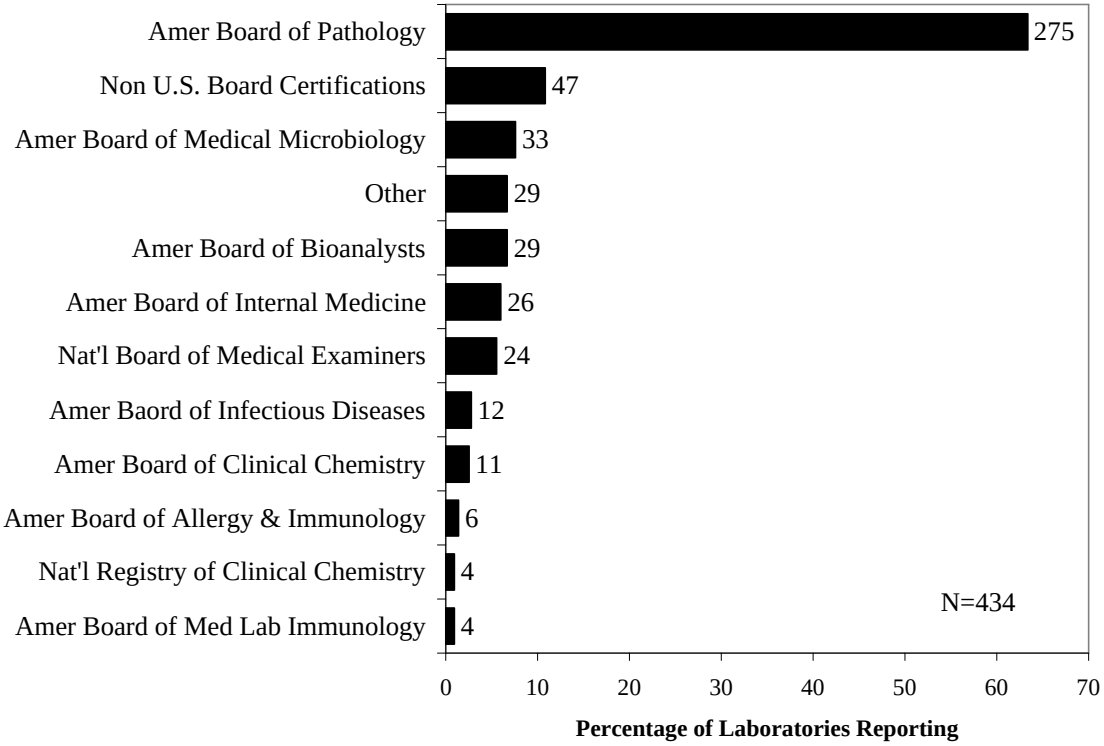
5. (a) Please choose the *highest academic degree* that has been awarded to your *Laboratory Director* and *Laboratory Supervisor* . (Choose only one degree for each person.) Note: MT(ASCP) is not an academic degree.



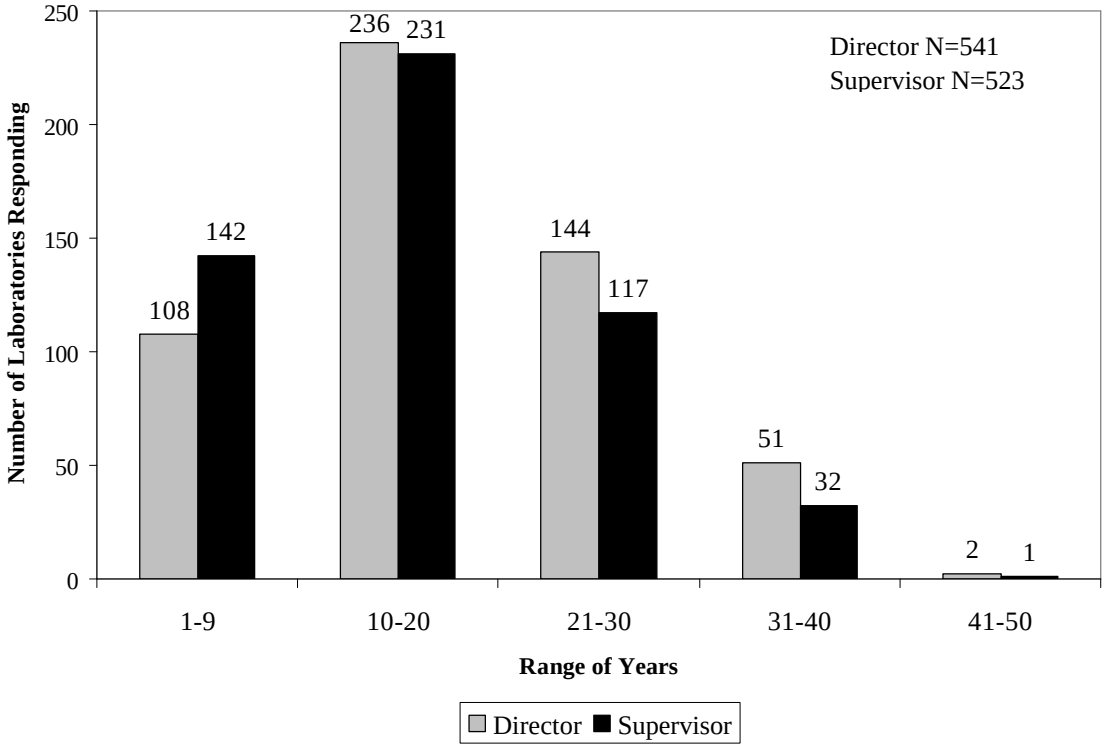
5.(b) If your *Laboratory Director* or *Laboratory Supervisor* has a degree other than M.D. or D.O., please indicate the academic discipline in which the degree was awarded. (Check all that apply.)



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



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



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

N=598

Supervisor on-site	Number of Laboratories (%)
Yes	588 (98.3%)
No	10 (1.7%)

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

N=10

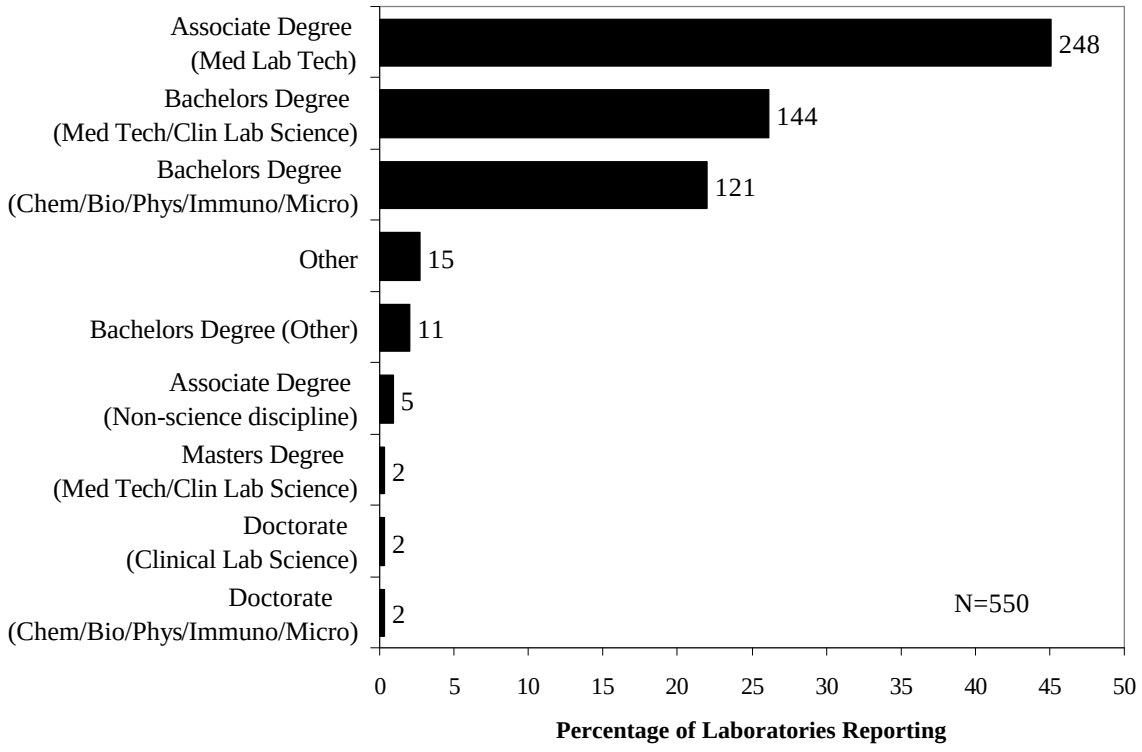
Someone other than Supervisor	Number of Laboratories (%)
Yes	8 (80.0%)
No	2 (20.0%)

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

N=608

Requirement	Number of Laboratories (%)
Minimum Education	556 (91.4%)
No Minimum Education	52 (8.6%)

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

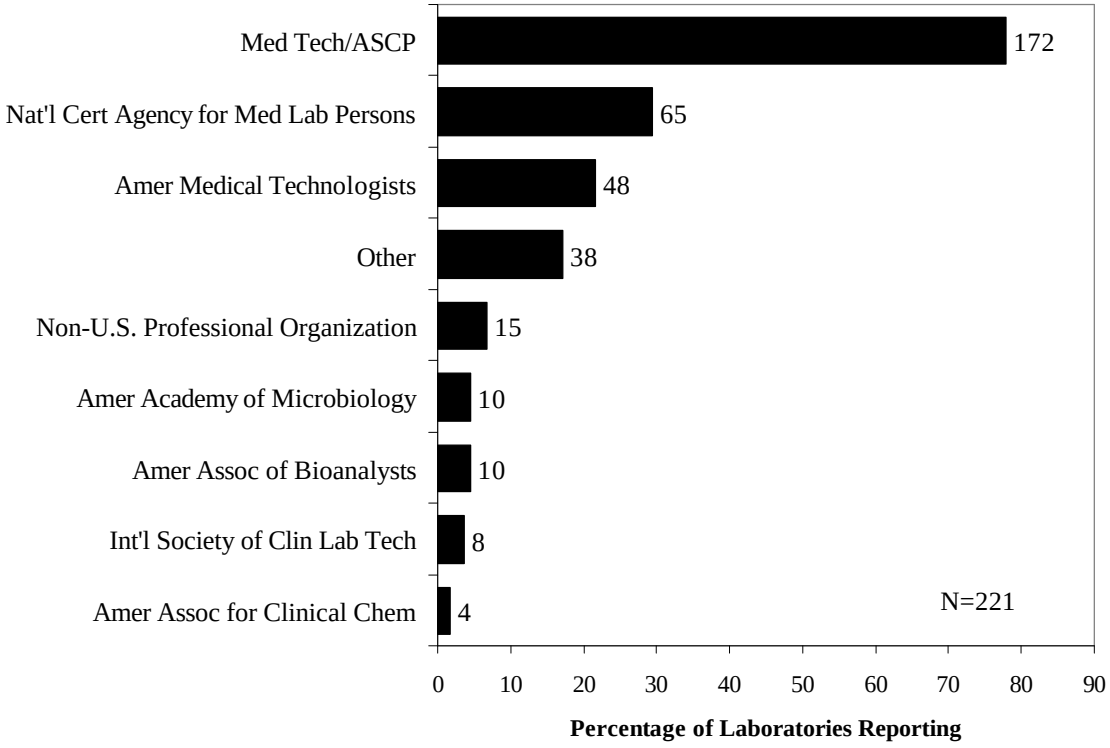


6. (c) Does your laboratory require that your HIV testing personnel have certification by a professional organization? (Do not include certification or licensing by city, state, or county.)

N=593

Requirement	Number of Laboratories (%)
Certification Required	224 (37.8%)
No Certification Required	369 (62.2%)

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

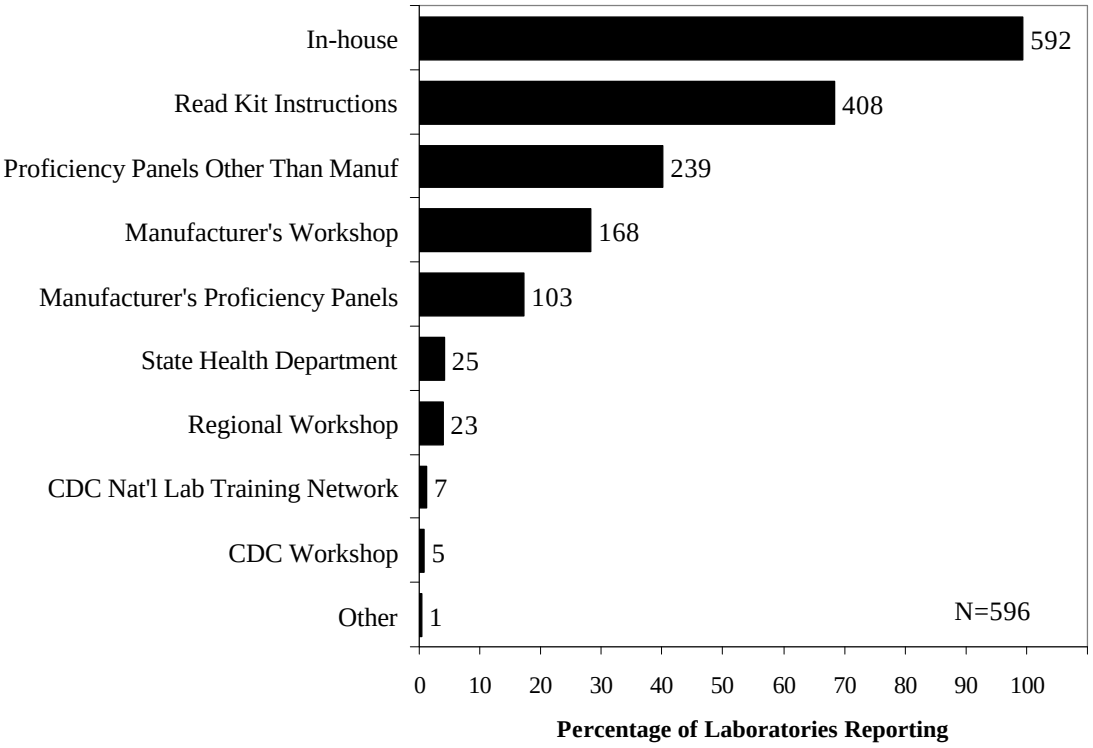


7.(a) Does your laboratory require personnel to have HIV-specific training in testing before they are considered qualified to perform tests?

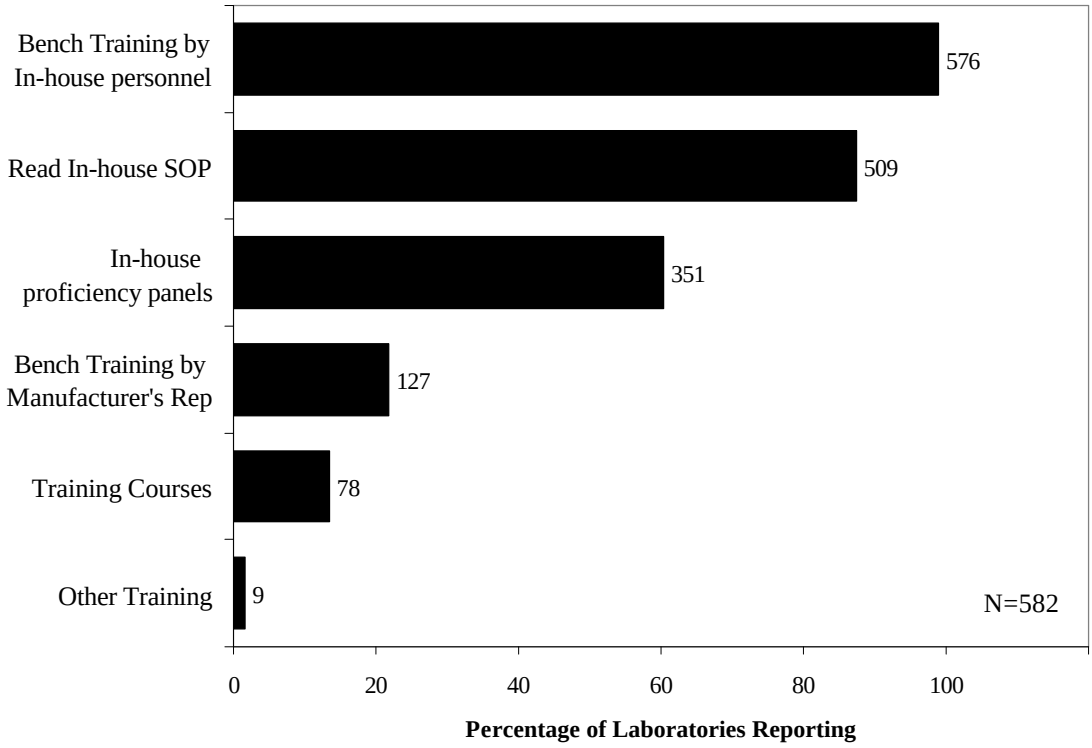
N=610

Training	Number of Laboratories (%)
HIV-Specific	599 (98.2%)
No Specific Training	11 (1.8%)

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



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



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

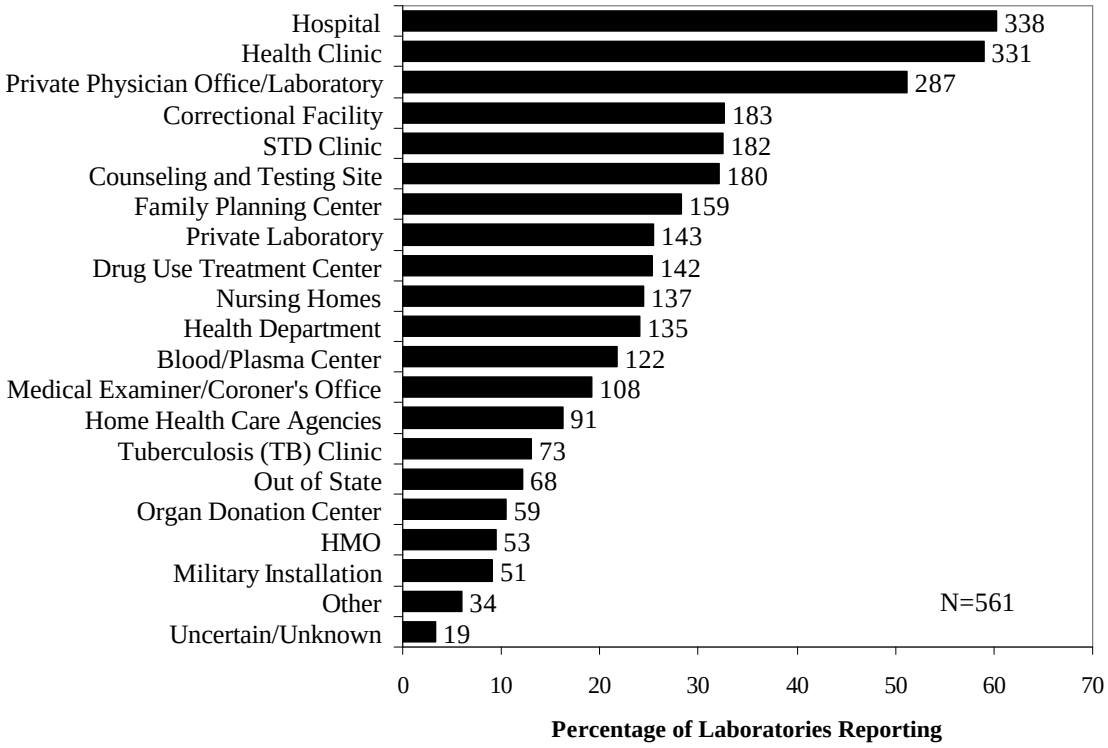
Type of Instruction	Instructions Not Provided	Written Instructions Provided by			
		Testing Laboratory	Associated Institution	Person Ordering Test	Other
Collecting	21 (3.6%)	492 (85.0%)	91 (15.7%)	31 (5.4%)	11 (1.9%)
Labeling	21 (3.6%)	490 (84.9%)	85 (14.7%)	27 (4.7%)	13 (2.3%)
Transporting	18 (3.1%)	494 (85.9%)	81 (14.1%)	22 (3.8%)	15 (2.6%)

9.(a) Where are the specimens collected for HIV 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.)

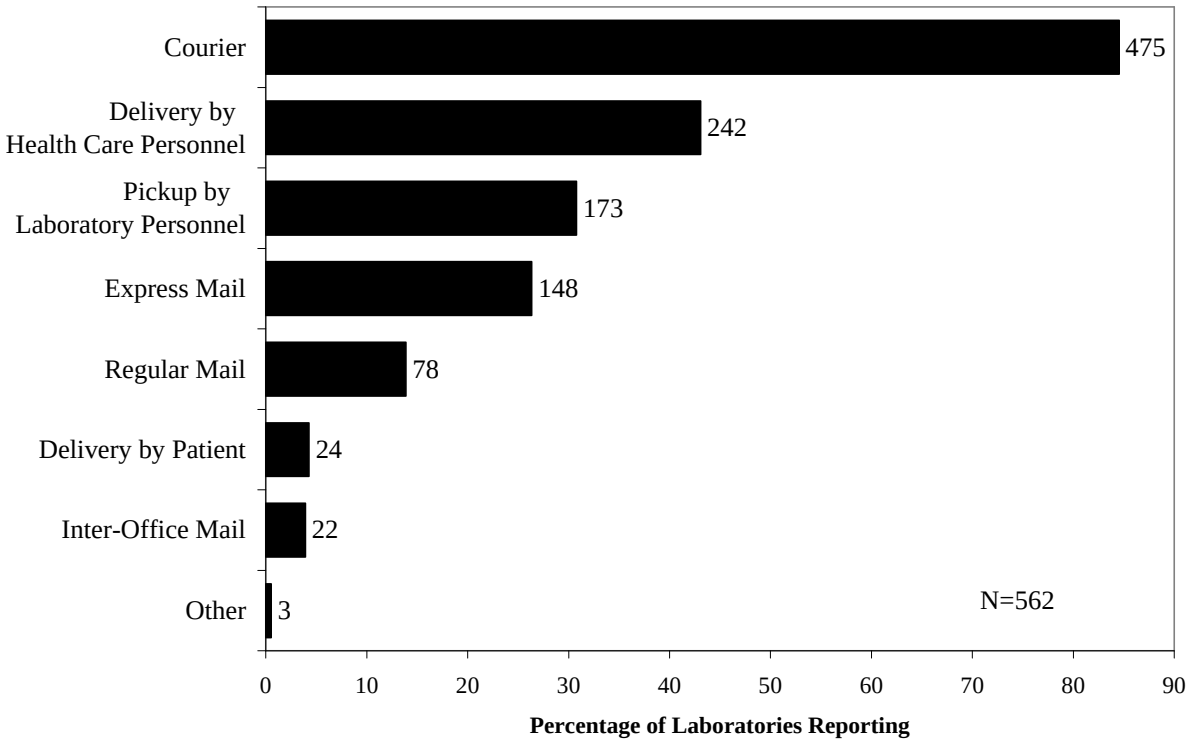
N=608

Site	Number of Laboratories (%)
Both on-site and off-site collection	402 (66.1%)
Off-site collection only	163 (26.8%)
On-site collection only	43 (7.1%)

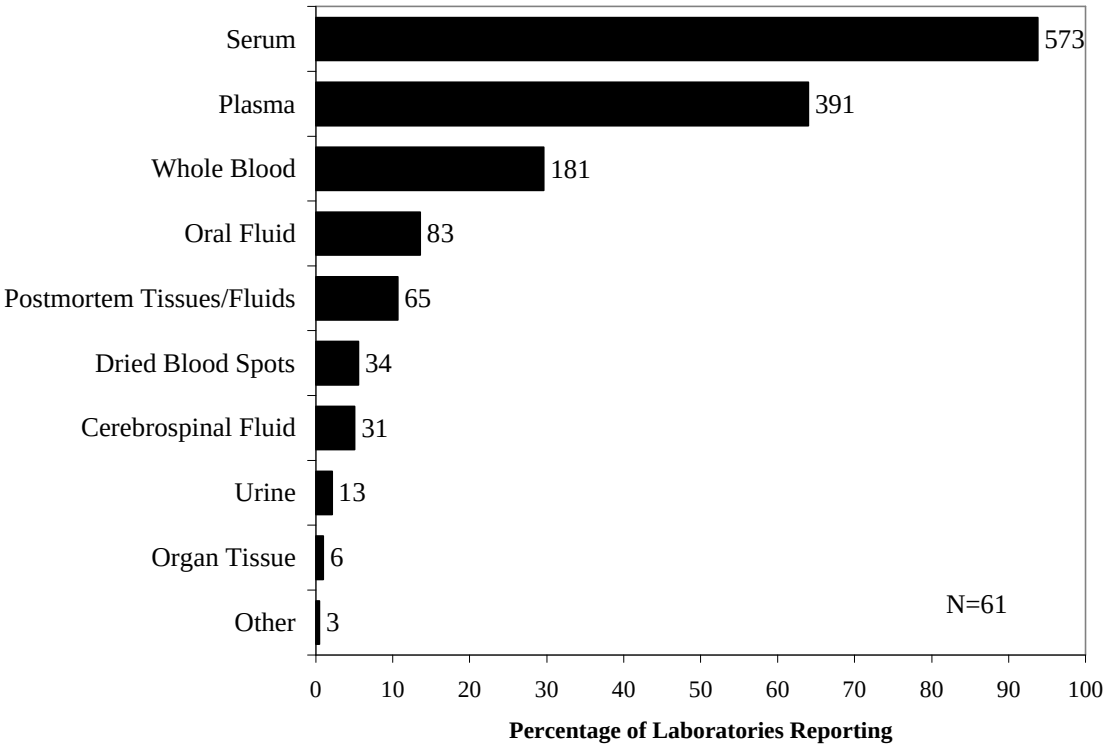
9.(b) If you perform HIV testing on specimens collected off-site, please indicate where they are collected. (Check all that apply.)



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 HIV infection? Please include all specimens test (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 HIV tests. (Check <u>all</u> that apply.)

N=593

Type of Instruction	Heat Inactivation	Clarification by Centrifugation or Filtration	No Pretreatment
Serum	5	27	526
Plasma	2	17	361
Whole Blood	0	16	171
Oral Fluid	0	14	68
Postmortem	0	8	50
Dried Blood Spots	0	3	33
Cerebrospinal fluid	0	0	37
Urine	0	0	20
Organ Tissue	0	0	12
Other	0	0	3

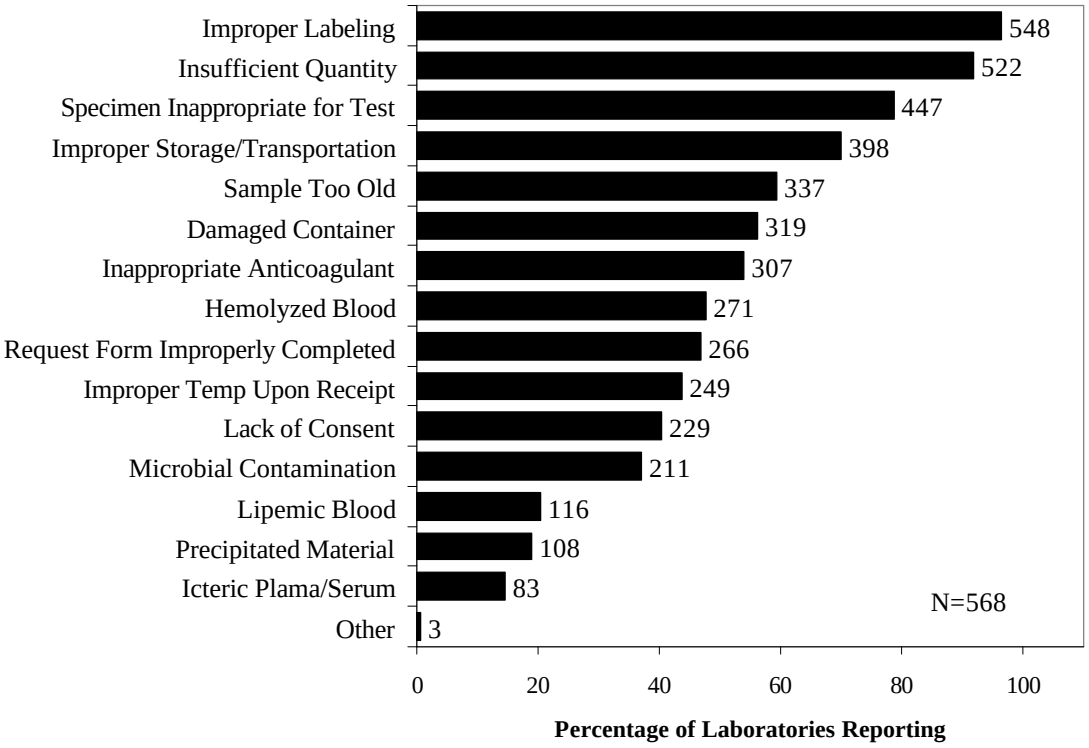
Note: The number in each column represents the number of laboratories that indicated the associated type of specimen.

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

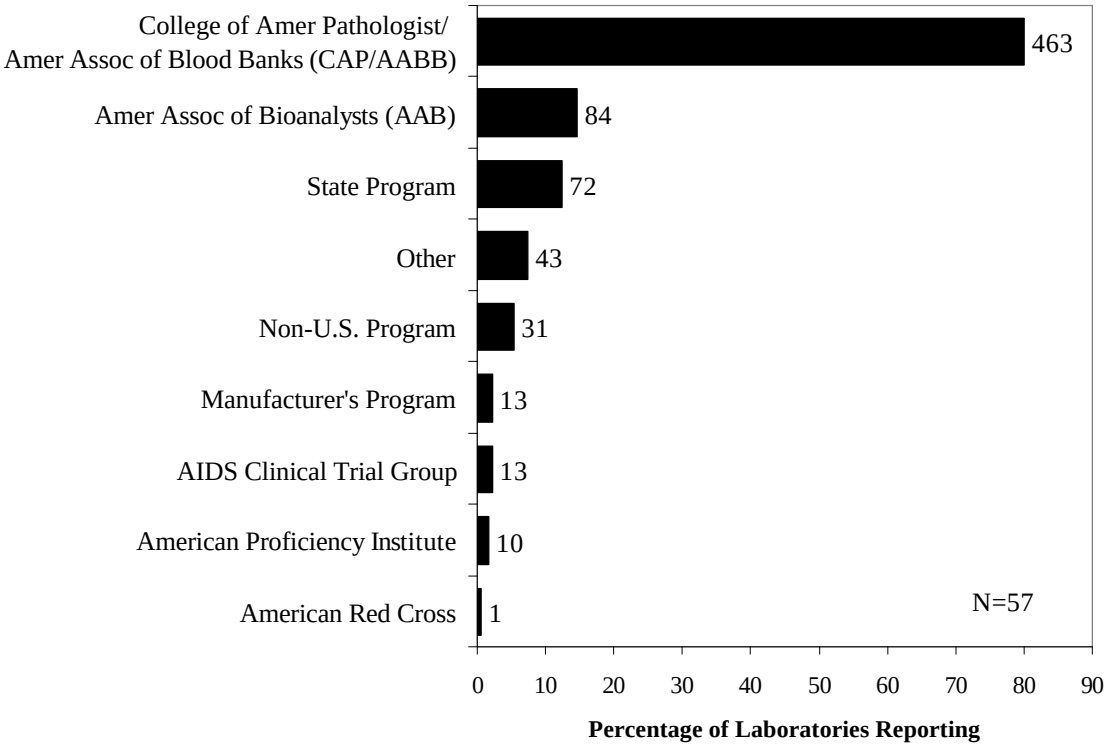
N=609

Written Pre-test Criteria for Unsatisfactory Specimens	Number of Laboratories (%)
Yes	571 (93.8%)
No	38 (6.2%)

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

Algorithms for HIV-1 Testing*

N=262

Step 1	Step 2	Step 3	Step 4	Step 5	Number of Laboratories	Percentage of Laboratories
EIA-S†	EIA-D†	WB			81	30.9
EIA-S	EIA-D	A			42	16.0
EIA-S	EIA-D	WB	A		20	7.6
EIA-S	EIA-D				11	4.2
EIA-S	A				10	3.8
EIA-S	EIA-D	WB	O		9	3.4
EIA-S	EIA-S	WB			7	2.7
EIA-S	EIA-D	IFA	A		6	2.3
EIA-S	EIA-D	WB	O	A	6	2.3
EIA-D	EIA-D	WB			4	1.5
EIA-D	WB				3	1.1
EIA-S	EIA-D	WB/A			3	1.1
EIA-S	EIA-D	IFA			3	1.1
EIA-S	EIA-n‡	WB			3	1.1
				Other Algorithms	54	20.6

Labels

Test

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

Footnotes

*A total of 59 unique algorithms were reported.
†EIA data in this table includes both manual and non-manual procedures.
‡EIA-n, non-manual selected without indication of duplicate or singly.

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.

Algorithms for HIV-1/HIV-2 Testing*

N=438

Step 1	Step 2	Step 3	Step 4	Step 5	Step 6	Number of Laboratories	Percentage of Laboratories
EIA-S†	EIA-D†	A				143	32.6
EIA-S	EIA-D					52	12.1
EIA-S	EIA-D	WB-1				46	10.5
EIA-S	EIA-D	WB-1	A			20	4.6
EIA-S	A					9	2.1
EIA-S	EIA-S	WB-1				8	1.8
EIA-S	EIA-D	WB-1/WB-2				7	1.6
EIA-S	EIA-D/A					7	1.6
EIA-S						6	1.4
EIA-S	EIA-D	WB-1	WB-2			6	1.4
EIA-S	EIA-D	WB-1	EIA-s‡	EIA-d	A	5	1.1
EIA-S	EIA-D	WB-1	O			4	0.9
EIA-S	EIA-D	WB-1	EIA-s	EIA-d	WB-1	4	0.9
					Other Algorithms	120	27.4

Labels

Test

EIA-S = HIV-1 Enzyme Immunoassay (EIA) Singly
EIA-s = HIV-2 Enzyme Immunoassay (EIA) Singly
EIA-D = HIV-1 EIA in duplicate
EIA-d = HIV-2 EIA in duplicate
WB-1 = HIV-1 Western Blot (WB)
WB-2 = HIV-2 Western Blot (WB)
O = test Other than HIV-1 EIA, IFA or WB
A = refer to another laboratory for Additional testing

Footnotes

*A total of 121 unique algorithms were reported.
†EIA data in this table includes both manual and non-manual procedures.
‡EIA non-manual selected without indication of duplicate or singly.

15. Please complete the following matrix table for the specific HIV tests that are performed in your laboratory. (Round to the nearest year. If less than one year, round off to one year.)

The number of <u>years</u> performing HIV tests

N=549

Range of Years	Type of Test Performed													
	HIV-1 EIA	HIV-1/2 EIA	HIV-2 EIA	HIV-1 WB	HIV-2 WB	HIV-1 IFA	HIV-2 IFA	HIV-1 RNA	HIV-1 DNA	HIV-1 PA	HIV-1 p24 Ag	HIV-1 Rapid Test	HIV-1 Viral Culture	Other
1-3	12	27	2	12	5	7	0	34	7	3	5	61	1	14
4-6	25	91	1	11	4	6	2	36	6	2	7	31	1	10
7-9	21	57	4	18	3	3	0	51	15	0	14	6	3	5
10-12	45	131	10	37	9	6	0	13	18	3	12	10	4	2
13-15	47	50	9	35	4	9	0	1	1	5	10	4	0	2
>15	97	33	2	96	3	13	1	1	0	7	8	1	7	0

Note: The number in each column represent the number of laboratories that indicated the associated range.

The number of <u>employees</u> currently performing specific HIV tests

N=539

Range of the Number Employees	Type of Test Performed													
	HIV-1 EIA	HIV-1/2 EIA	HIV-2 EIA	HIV-1 WB	HIV-2 WB	HIV-1 IFA	HIV-2 IFA	HIV-1 RNA	HIV-1 DNA	HIV-1 PA	HIV-1 p24 Ag	HIV-1 Rapid Test	HIV-1 Viral Culture	Other
1- 2	46	67	11	72	15	12	2	39	19	5	16	13	3	12
3-4	63	121	8	55	6	13	1	48	11	4	13	14	7	9
5-6	43	95	4	35	3	4	0	26	7	4	7	16	3	5
7-8	27	38	1	19	1	3	0	10	2	3	5	12	0	5
9-10	7	24	3	7	0	4	0	5	0	1	0	17	0	0
>10	11	45	0	10	0	0	0	5	2	0	5	32	1	2

Note: The number in each column represent the number of laboratories that indicated the associated range.

16. 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=578

Source of procedure	Test Types			
	EIA	WB	IFA	OTHER
In house Written Protocol	451	176	34	34
Manufacturers Insert	520	200	38	34
No Written Procedure	0	1	1	3
Other Sources	23	12	2	4
State Health Department	30	13	2	0

Note: The numbers in each column represent the number of laboratories that indicated the associated source of procedure.

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

N=581

Western Blot Testing	Number of Laboratories (%)
Yes	234 (40.3%)
No	347 (59.7%)

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

N=232

Band Patterns	Number of Laboratories	Percentage of Laboratories
Any two of p24, gp41, gp120/gp160	198	85.3
p24 plus gp41	1	0.4
p24 plus p31, and gp41 or gp120/gp160	2	0.9
Two env bands w/ or w/o gag or pol bands	14	6.0
p24 or p31, and gp41 or gp120/gp160	3	1.3
One protein from three gene groups: Gag (p17, p24, p55) Env (gp41, gp120, gp160), or Pol (p31, p51, p65/66)	5	2.2
Other	9	3.9

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

N=231

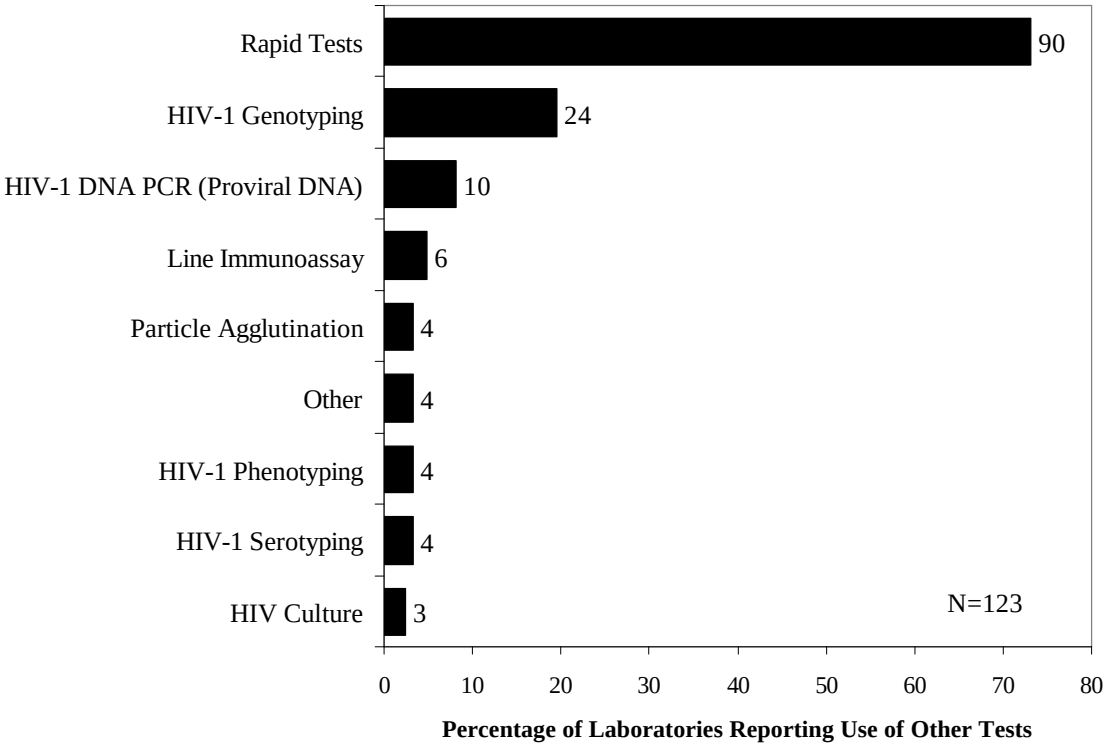
Band Patterns	Number of Laboratories	Percentage of Laboratories
No HIV-1 specific bands	64	27.7
No bands present	164	71.0
Other	3	1.3

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

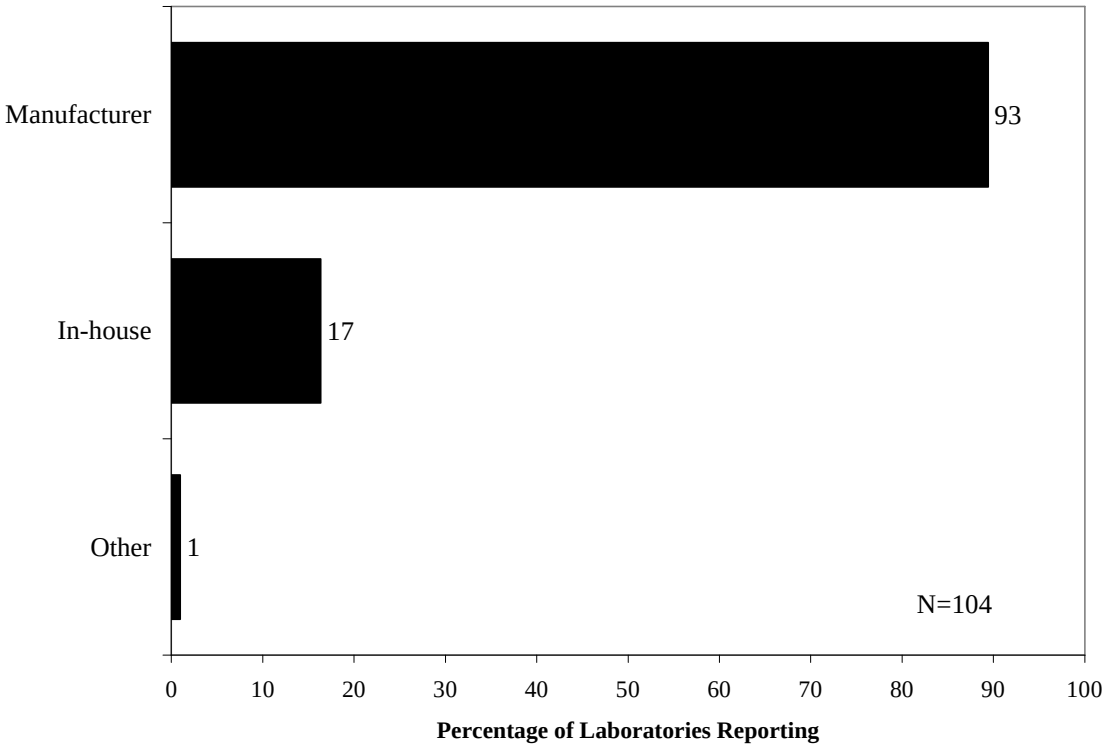
N=578

Other Tests	Number of Laboratories (%)
Yes	131 (22.7%)
No	447 (77.3%)

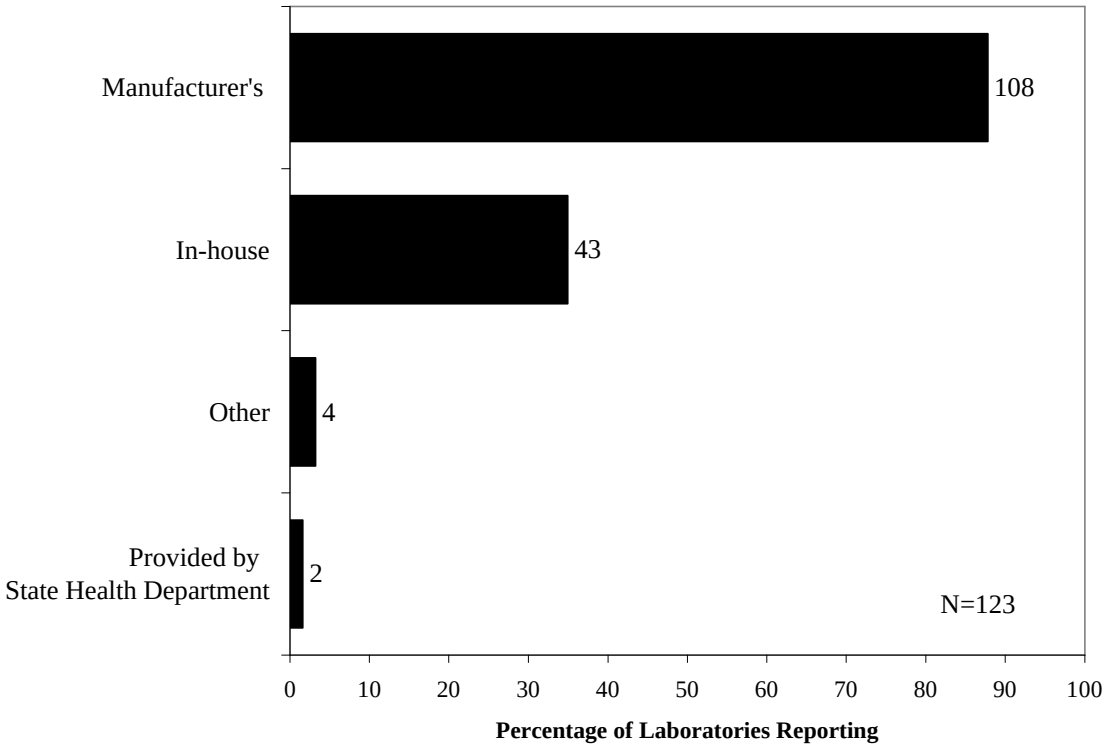
18.(b) If yes, indicate below the other HIV tests performed in your laboratory. (Check all that apply.)



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



18.(d) What procedure does your laboratory follow for performing HIV tests <u>other than</u> EIA, WB, IFA, P24 Ag, and RNA? (Check <u>all</u> that apply.)



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

N=578

Used External Controls	Number of Laboratories (%)
Yes	427 (73.9%)
No	151 (26.1%)

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=425

Test Method	Each Test*	Each Run†	Two Each Day	Each New Lot	Other Frequency
EIA	167	205	68	52	11
IFA	2	14	2	8	1
WB	6	80	5	40	3
OTHER	7	32	6	12	3

*An EIA plate, Western blot strip or IFA slide

†A set of EIA plates, Western blot strips or IFA slides

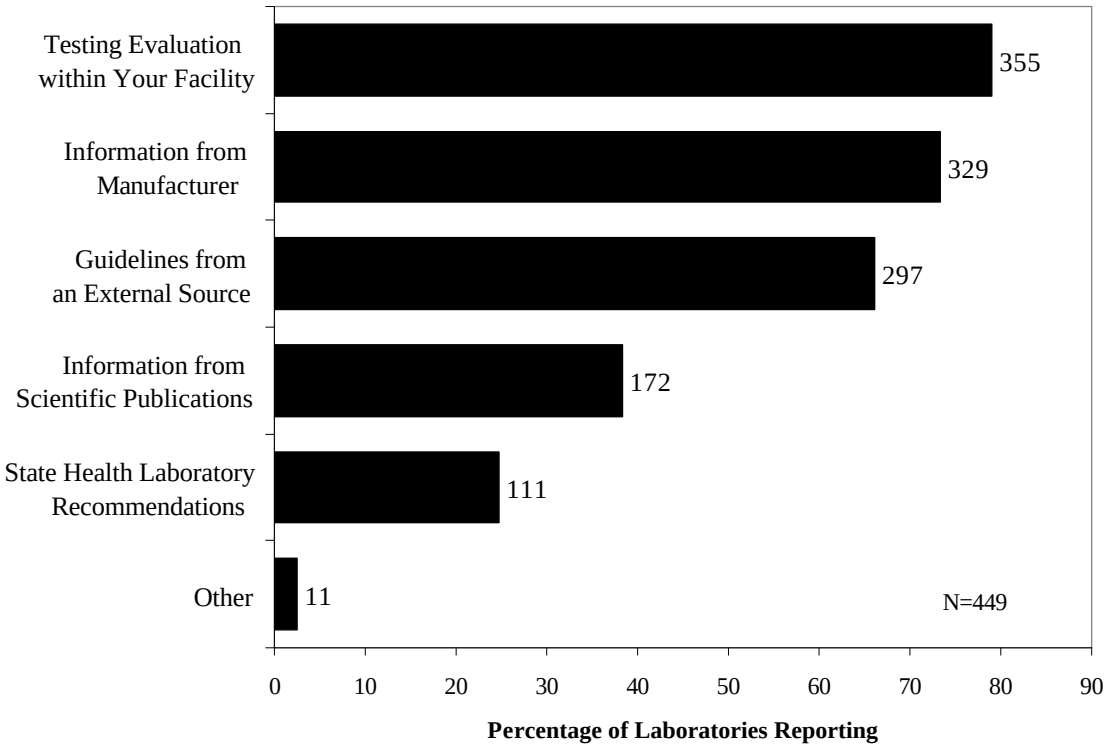
Note: The numbers in each column represent the number of laboratories that indicated the associated test method.

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

N=576

Written Validation Protocol	Number of Laboratories (%)
Yes	459 (79.7%)
No	117 (20.3%)

20.(b) If yes, please identify the methods used for establishing these written criteria. (Check <u>all</u> that apply.)



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

N=561

QA Plan that Includes HIV Testing	Number of Laboratories (%)
Yes	498 (88.8%)
No	63 (11.2%)

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

N=488

Written Policies for Monitoring HIV QA	Number of Laboratories (%)
Yes	449 (92.0%)
No	39 (8.0%)

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=550

Number of Tests Performed During Most Recent Representative Month	Total Specimens Tested	Reactive by Screen	Tested by Suppl/Conf	Reactive by Suppl/Conf
<10	2	224	203	198
10-99	67	188	174	126
100-999	258	49	51	38
1,000-9,999	178	4	4	1
10,000-99,999	42	1	0	0
>99,999	3	0	0	0

Note: The numbers in columns 2, 3, 4 and 5 represent the number 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=573

Days Elapsed	From Collection to Receipt in Laboratory	From Receipt to Specimen Tested	From Specimen Tested to Results Reported
1	453	317	416
2-3	93	199	94
4-5	8	24	24
6-7	4	18	3
>7	6	5	7

Note: The numbers in columns 2, 3, and 4 represent the number 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=384

Amount Charged by the Laboratory	Test Type			
	EIA	WB	IFA	Other
<$50	230	56	10	19
$50-99	100	53	6	8
$100-149	34	27	5	7
$150-200	7	15	1	2
>$200	9	9	0	5

Note: The numbers in columns 2, 3, 4 and 5 represent the number of laboratories that indicated the associated range.

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

N=574

Specimen Referrals	Number of Laboratories (%)
Additional Testing	455 (79.3%)
No Additional Testing	119 (20.7%)

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

N=449

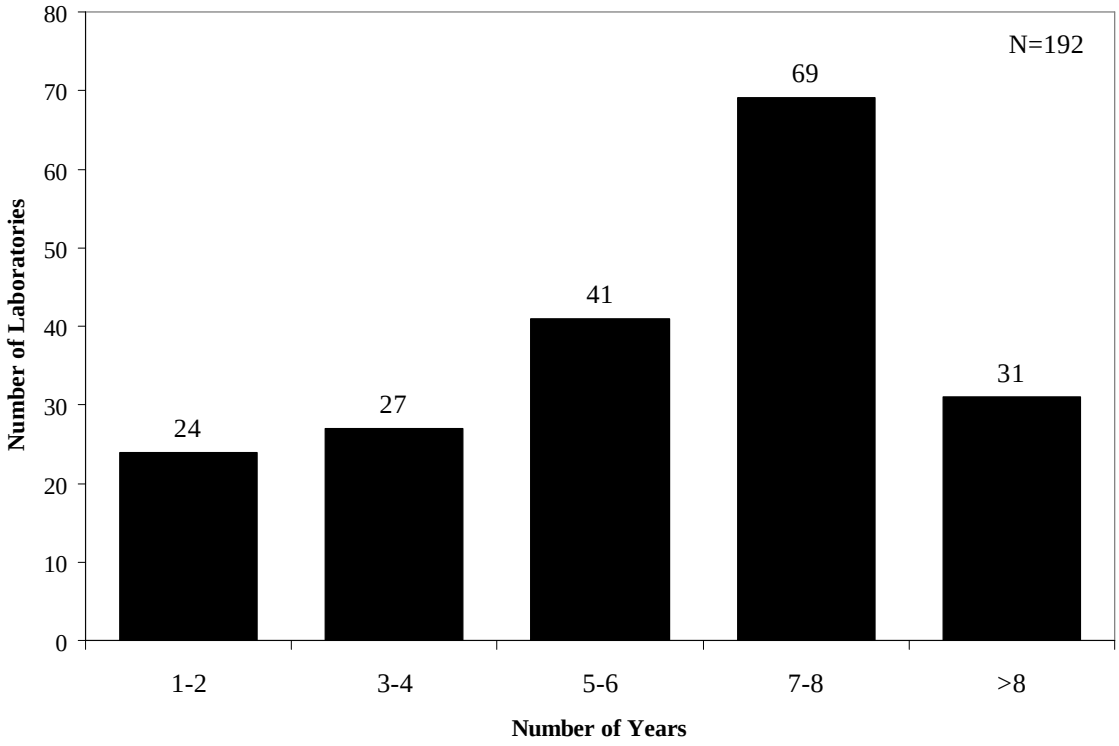
	Referral Laboratory Type					
Test Type	**Hospital**	**Health Department**	**Blood Bank**	**Independent**	**Other**	**Total**
WB HIV-1	15	55	21	221	19	331
WB HIV-2	4	41	9	184	27	265
HIV-1 RNA	12	13	10	109	8	152
HIV-1 DNA	10	9	3	107	7	136
EIA HIV-2	3	23	18	76	9	129
HIV-1 p24 Antigen	6	8	1	92	8	115
Antiretroviral Resistance	5	7	1	89	4	106
EIA HIV-1 HIV-2	7	15	2	37	14	75
Viral Culture	1	3	0	40	1	45
EIA HIV-1	3	14	6	14	3	40
IFA HIV-1	23	15	1	1	0	40
IFA HIV-2	1	8	0	24	0	33
Other	3	3	2	9	7	24
Particle Agglutination	0	2	0	16	0	18

Note: The numbers in the columns represent the number of laboratories that indicated each referral laboratory type.

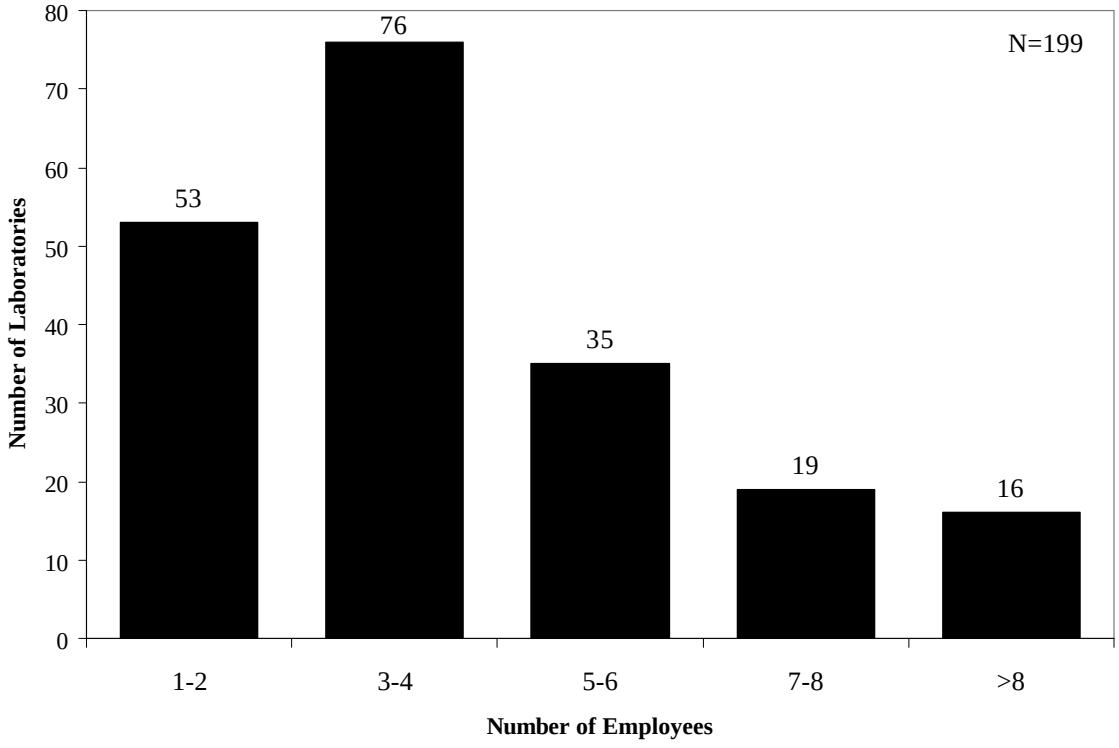
The following charts and tables refer only to RNA testing.

25. Please complete the following table for the HIV-1 RNA testing performed in your laboratory. (Round to the nearest year. If less than one year, round off to one year.)

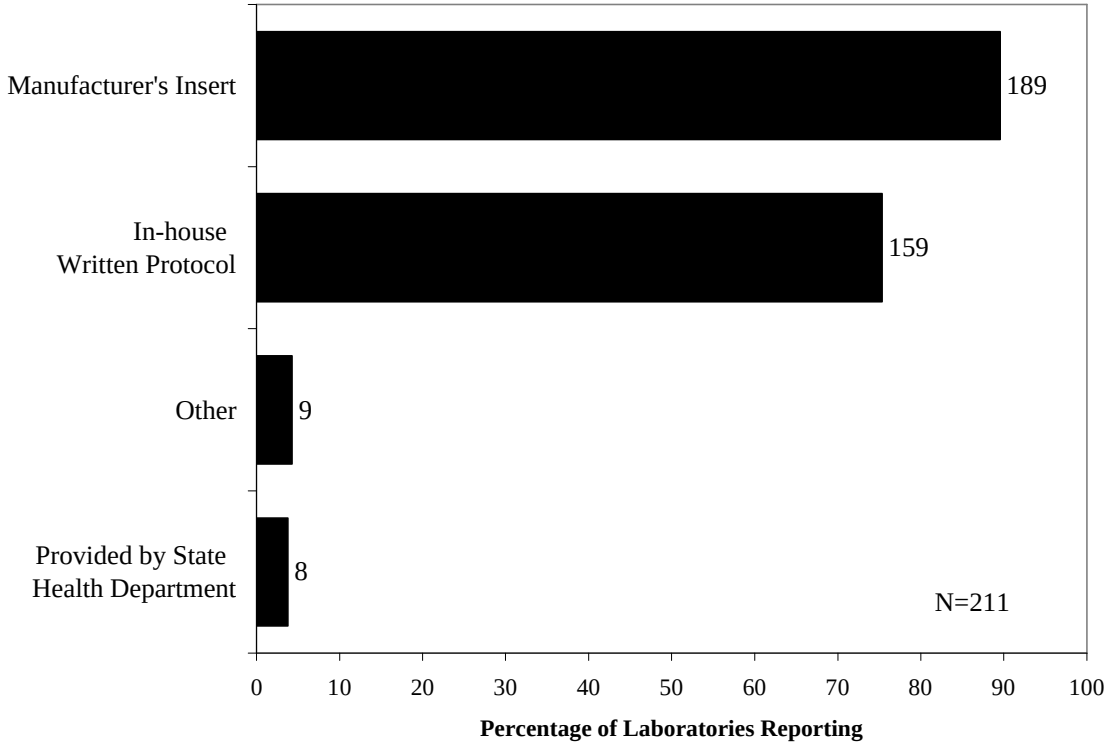
The number of years the laboratories performed HIV-1 RNA testing



The number of employees currently performing HIV-1 RNA testing



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

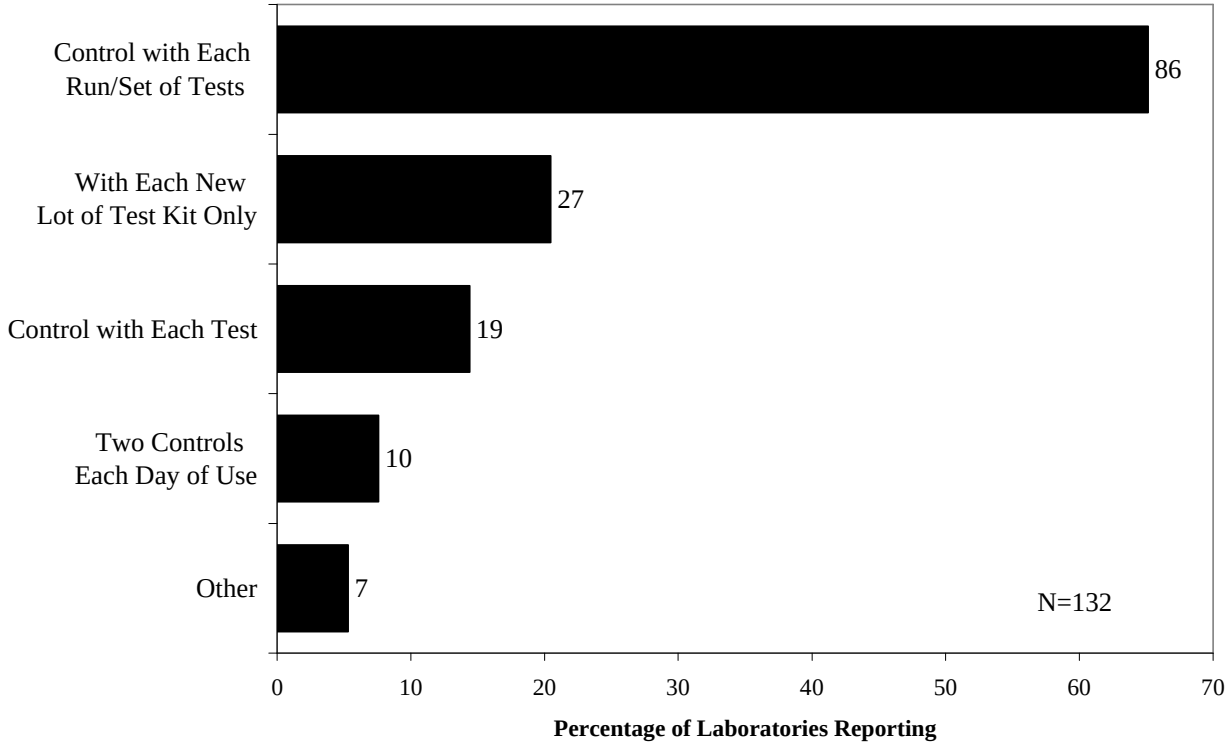


27.(a) Does your laboratory use controls in addition to the kit manufacturer controls (external controls)?

N=210

External Controls	Number of Laboratories (%)
Yes	134 (63.8%)
No	76 (36.2%)

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 <u>all</u> that apply.)

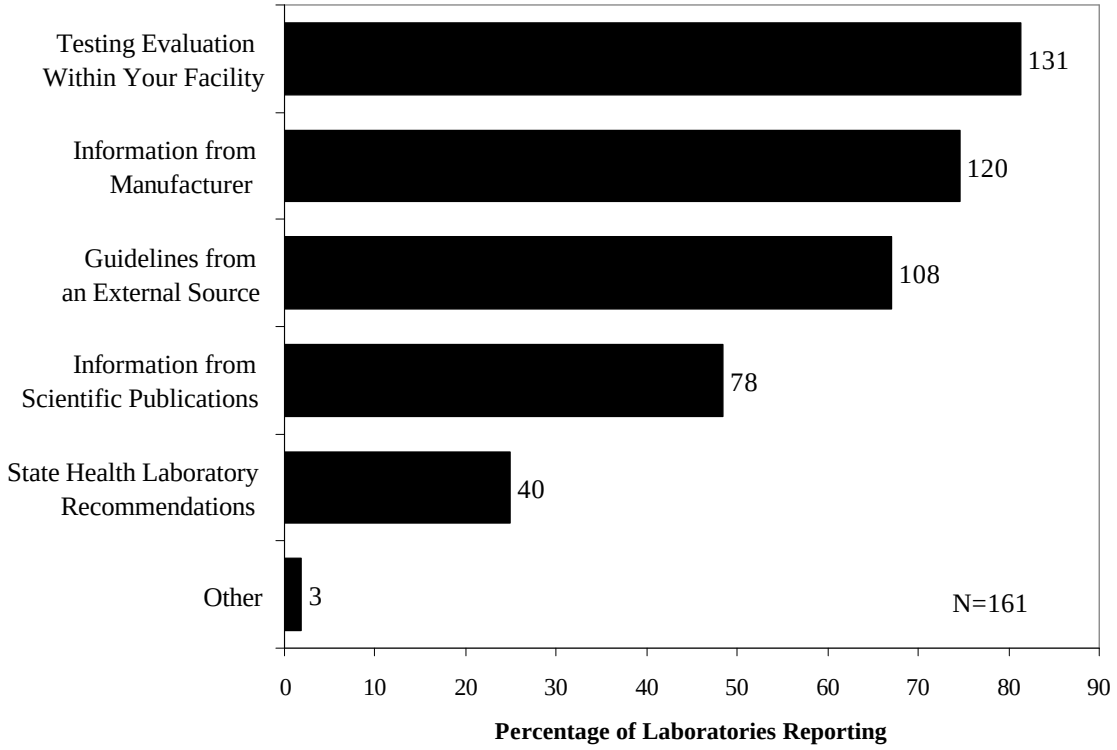


28.(a) Does your laboratory have <u>written criteria</u>, such as a validation protocol, for adopting a new test or a different manufacturer's test for HIV-1 RNA testing?

N=207

Validation Protocol	Number of Laboratories (%)
Yes	162 (78.3%)
No	45 (21.7%)

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



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

N=204

QA Program	Number of Laboratories (%)
Yes	179 (87.7%)
No	25 (12.3%)

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

N=179

Monitoring QA	Number of Laboratories (%)
Written Policies/Procedures	169 (94.4%)
No Written Policies/Procedures	10 (5.6%)

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 for HIV-1 RNA during the most recent representative month. (Round off to the nearest whole number.)

The Number of Specimens Tested

N=199

Number of Tests Performed During Most Recent Representative Month	Total # of Laboratories
<10	7
10-99	34
100-999	118
1,000-9,999	28
10,000-99,999	12

The Percentage of Specimens with HIV-1 RNA Detected

Percentage of HIV-1 RNA Positive Specimens*	Total # of Laboratories
<10	25
10-20	3
21-30	3
31-40	7
41-50	23
51-60	29
61-70	28
71-80	23
81-90	13
91-100	15

*The percentages were calculated from the laboratories' responses to the total number of tests performed and the number of specimens with HIV-1 RNA detected (# of RNA positive/total tests performed x 100).

Note: The number in column two represents the number 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=204

Days Elapsed	From Collection to Receipt in Laboratory	From Receipt to Specimen Tested	From Specimen Tested to Results Reported
1-3	193	125	166
4-6	4	44	22
7-9	0	18	7
10-12	0	8	3
13-14	1	5	0
>14	0	4	0

Note: The numbers in columns 2, 3, and 4 represent the frequency of laboratories that indicated the associated range.

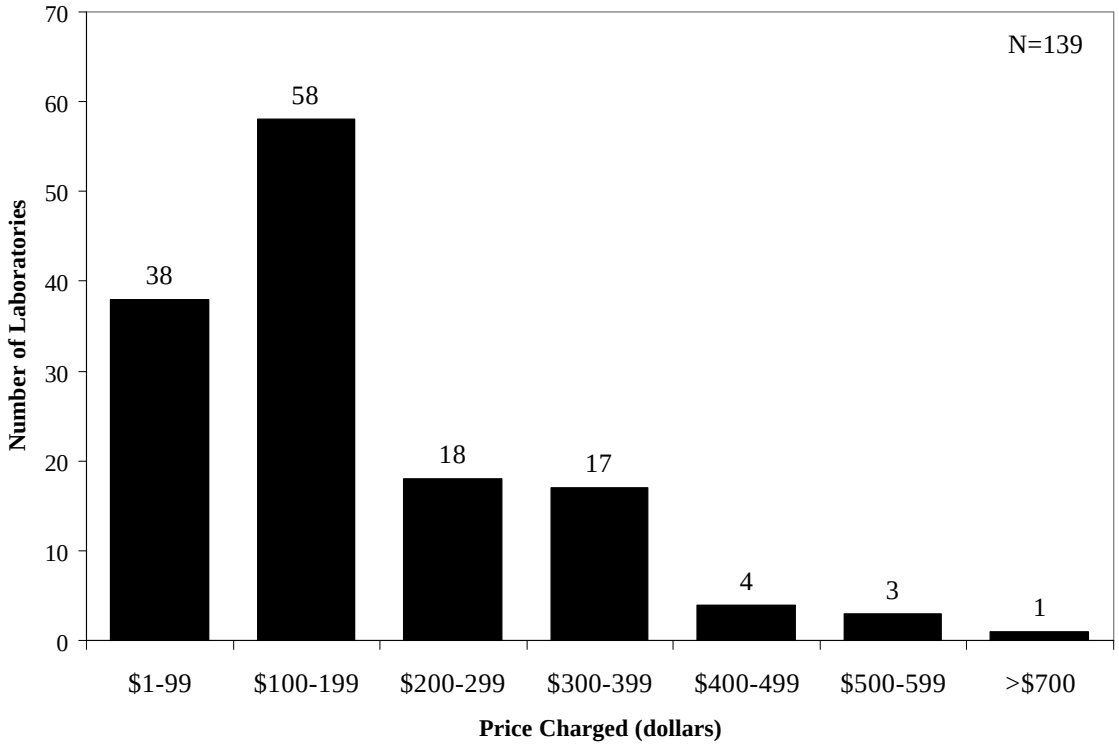
31. What is the temperature of specimens received by your laboratory? (Check <u>all</u> that apply to <u>HIV-1 RNA specimens received only in your laboratory</u>.)

N=205

Type of Specimen	Frequency of Laboratories Responding*		
	Ambient	2-4 °C (Refrigerated)	Frozen
Cerebrospinal Fluid	8	8	16
Dried Blood Spots	6	0	0
Other	1	1	3
Plasma	69	76	123
Serum	15	19	23
Whole Blood	69	20	2

Note: The numbers in column represent the number 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=205

Specimens Referred	Number of Laboratories (%)
Yes	61 (29.8%)
No	144 (70.2%)

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 all that apply.)

N=57

Test Type	Laboratory Type					Total
	Hospital	Health Department	Blood Bank	Independent	Other	
Antiretroviral Resistance	2	4	0	24	4	34
HIV-1 DNA	1	4	0	15	2	22
Other	3	0	1	7	3	14
WB HIV-2	1	2	0	11	0	14
WB HIV-1	2	2	1	6	0	11
EIA HIV-2	0	2	1	5	0	8
EIA HIV-1/HIV-2	2	1	0	5	0	8
HIV-1 p24 Antigen	1	0	0	3	0	4
Viral Culture	1	1	0	2	0	4
EIA HIV-1	0	2	0	1	0	3
IFA HIV-1	0	0	0	2	0	2
IFA HIV-2	0	0	0	2	0	2
Particle Agglutination	0	0	0	0	0	0

Note: The numbers in the columns represent the number of laboratories that indicated each referral laboratory type.

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