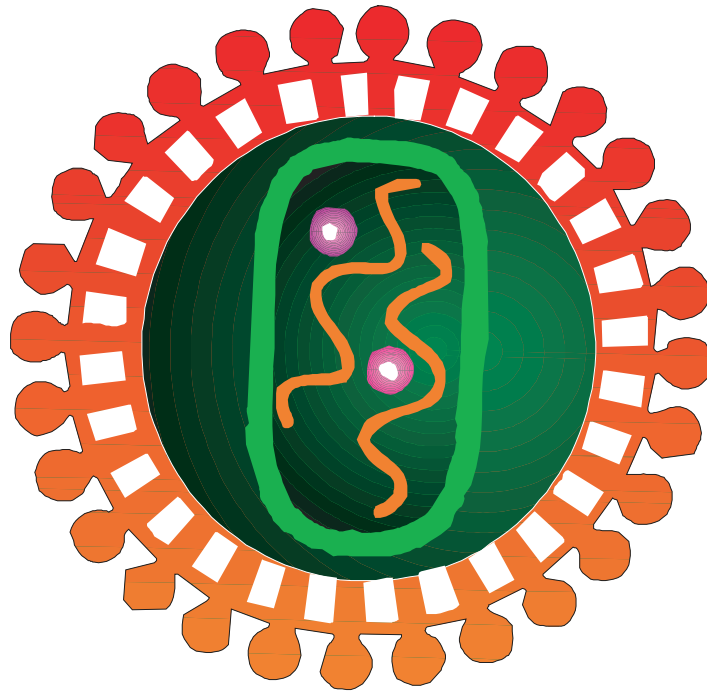




Questionnaire Results:
HIV Rapid Testing
Survey 2004



DEPARTMENT OF HEALTH & HUMAN SERVICES



HIV-1 Rapid Testing MPEP Survey Questionnaire August 2004 Report of Results

Report of the August 2004 Human Immunodeficiency Virus Type 1 (HIV-1) Rapid Testing (RT) Survey Questionnaire Results Provided by Participant Facilities in the Model Performance Evaluation Program (MPEP), Centers for Disease Control and Prevention (CDC).

Coordination of report production

The production of this report was coordinated in CDC by:

Coordinating Center
for Health Information and Service..... Ed Sondik, Ph.D.,
Blake Caldwell, M.D., M.P.H., Directors

National Center for Health Marketing..... Steve Solomon, M.D., Director

Division of Public Health Partnerships..... Robert Martin, M.P.H., Dr. P.H., Director

Laboratory Practice Evaluation and
Genomics Branch..... Devery Howerton, Ph.D., Chief

Report content

The material in this report was developed and prepared by:

Model Performance Evaluation Program (MPEP)..... Laurina O. Williams, Ph.D., M.P.H.,
Co-Manager

..... G. David Cross, M.S., Co-Manager

MPEP HIV-1 Rapid Testing Performance Evaluation..... Leigh Inge Vaughan, B.A.,
HIV Rapid Testing Project Coordinator

Use of trade names and commercial sources is for identification only and does not constitute endorsement by the Public Health Service or the U.S. Department of Health and Human Services.

Contact information

Inquiries should be directed to the Model Performance Evaluation Program by calling Dr. Laurina Williams at (770) 488-8130 or Leigh Vaughan at (770) 488-8095.

Executive Summary of Results

HIV Rapid Testing Questionnaire Survey, August 2004

Survey Description

The accompanying report details the results from the CDC Model Performance Evaluation Program (MPEP) HIV Rapid Testing Practices Survey conducted during 2004. The laboratory practices survey was sent to all testing sites enrolled in the MPEP HIV rapid (HIV-RT) testing program. Completed questionnaires were submitted by 263 (59.0%) of the 446 HIV-RT testing sites enrolled. The distribution of respondents compared with non-respondents was constant for testing site types (63% respondents vs. 37% non-respondents) with the exception that among health departments, half responded and half did not. The survey participants included 236 U.S. testing sites and 27 non-U.S. testing sites.

Results Summary

Survey Participants

Most survey respondents were from hospital laboratories (63%). However, a variety of testing sites that could be considered point-of-care sites were also represented (Figure 1a). Survey participants also tended to accept and perform HIV rapid tests on specimens that were collected in a variety of point-of-care testing sites such as community-based organizations, counseling and testing centers, and family planning centers (Figure 7b). Within hospitals, the reporting of a variety of secondary testing sites indicated (Figures 1a and 7b) that HIV rapid testing was being used for different purposes including post-exposure treatment, voluntary testing, screening, and testing pregnant women (Figure 3a).

Test Volume

The median number of HIV rapid tests performed in the most recent representative month calculated from the responses was 10, although the range was from 0 - 3700 tests (Figure 3d). Most of the U.S. testing sites (77%) reported that none of the HIV rapid tests performed on client/patient specimens in the most recent representative month were positive. Although numbers are small, nearly half (46%) of the non-U.S. testing sites reported that >11 HIV rapid tests were positive in the most recent representative month (Figure 3e).

Test Kits

The predominant kit types used by U.S. testing facilities were OraQuick Rapid HIV-1 Ab tests (55%) and MedMira Reveal or Reveal G2 (40%). (Note that these data reflect the types of test kits that were available on the U.S. market at the time of the survey.) The predominant kit type used by non-U.S. testing sites was Abbott Determine HIV-1/2 (70%); although a variety of kit types were reported by these testing facilities (Figure 5). Participants generally performed other HIV tests in their facilities, and HIV rapid tests did not tend to replace other methods (Figures 8 and 9).

Testing Personnel

In these testing sites, HIV rapid tests were primarily performed by medical technologists, medical technicians, and persons with a BS/BA in laboratory sciences, HIV counselors or persons with an associate's degree (Figure 10). This is reflective of the types of facilities participating, with the majority being hospitals. Most participants (88%) reported that training on rapid HIV testing was conducted in-house. The median length of training was for two hours (Figure 11). Most facilities (75%) provided onsite counseling to clients/patients

(Figure 14e), and most counseling was provided by physicians, counselors, RN/LPNs or nurse practitioners (82% of total responses; Figure 14f).

Confirmatory Testing

Most participants (96%) reported that confirmatory testing was performed either within their facility or at another facility on initially reactive (preliminary positive) results, although 4% answered “no” to this question, implying that no confirmatory testing was performed (Figure 12a). At least 10/203 (5%) U.S. testing sites describing methods used for confirmatory testing do not use either Western blot (WB) or an indirect immunofluorescence assay (IFA), the confirmatory methods recommended by current CDC guidelines (Figure 12b). (1, 2) The reasons for not using the recommended confirmatory test methods are unclear.

Quality Control

Most facilities (80%) said they ran quality control samples when performing HIV rapid testing. Participants could give more than one response to this question. However, it is of concern that 20% of participants reported never running quality control samples. Most of these were U.S. testing sites. Running quality control samples as a part of an overall quality assurance system is recommended.(1)

Conclusion

The CDC HIV-RT MPEP supports improving the quality of public health by continuously improving laboratory testing. This second CDC HIV-RT MPEP laboratory practices survey was carried out about 20 months after new CLIA-waived HIV rapid testing kits were approved by the U.S. Food and Drug Administration and were available in the United States. CDC HIV-RT MPEP will continue to monitor changes in laboratory practices in HIV rapid testing.

The results presented here reflect a wide range of laboratory/testing site practices in HIV rapid testing among MPEP participants. With changing and evolving testing practices, HIV testing sites should be especially concerned about quality assurance, and should be aware of existing guidelines and recommendations. Recommendations for an overall quality assurance program for HIV rapid testing sites and for best laboratory practices can be found on the MPEP website: <http://www.phppo.cdc.gov/mpep>.

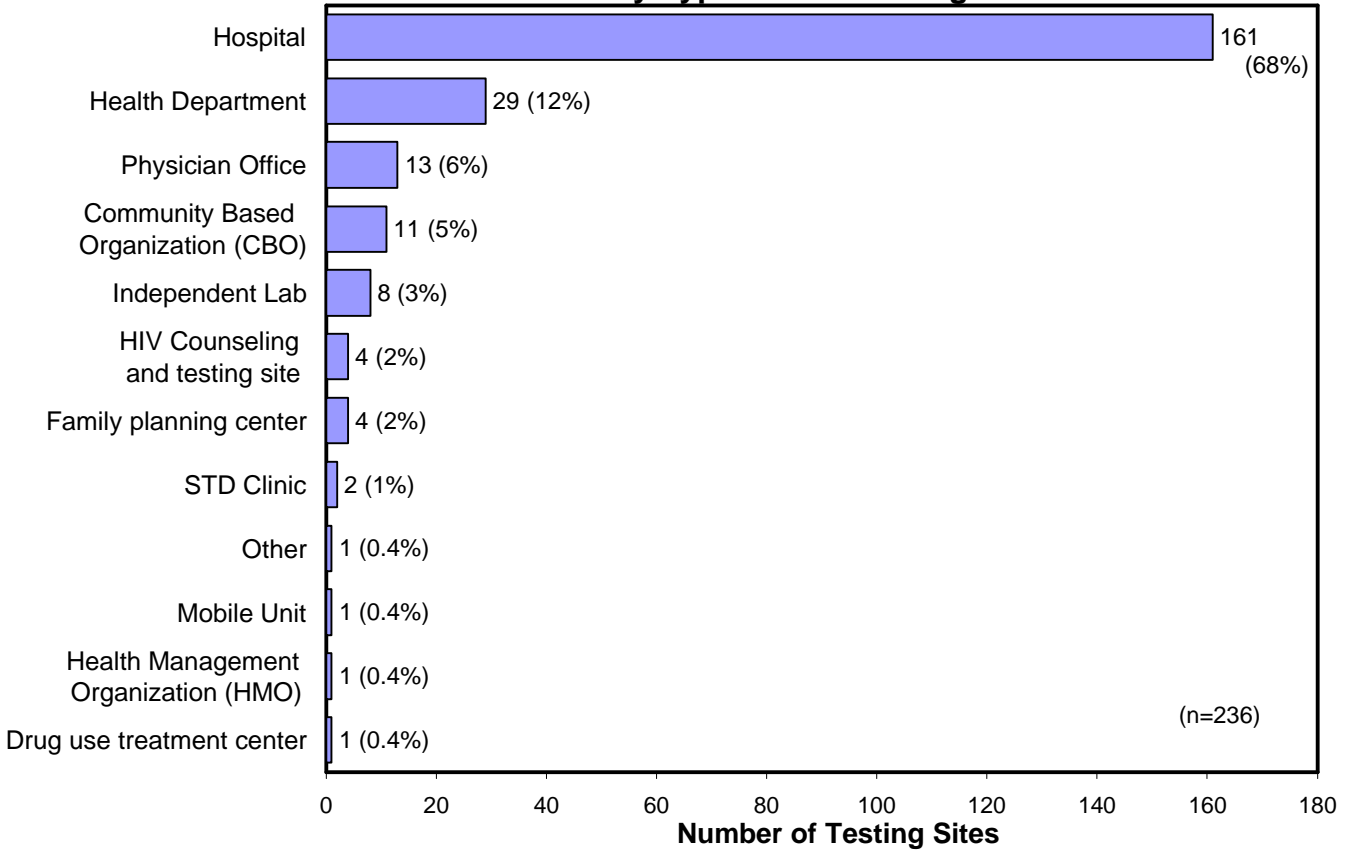
References:

- 1) Quality Assurance Guidelines for Testing Using the OraQuick Rapid HIV-1 Antibody Test. Centers for Disease Control and Prevention, U.S. Department of Health and Human Services. 2003. http://www.cdc.gov/hiv/rapid_testing/materials/QA-Guide.htm.
- 2) CDC. Notice to Readers: Protocols for Confirmation of Reactive Rapid HIV Tests MMWR Recommendations and Reports. 2004; 53(10); 221- 222. <http://www.phppo.cdc.gov/mpep/HIV-1rt.aspx>.

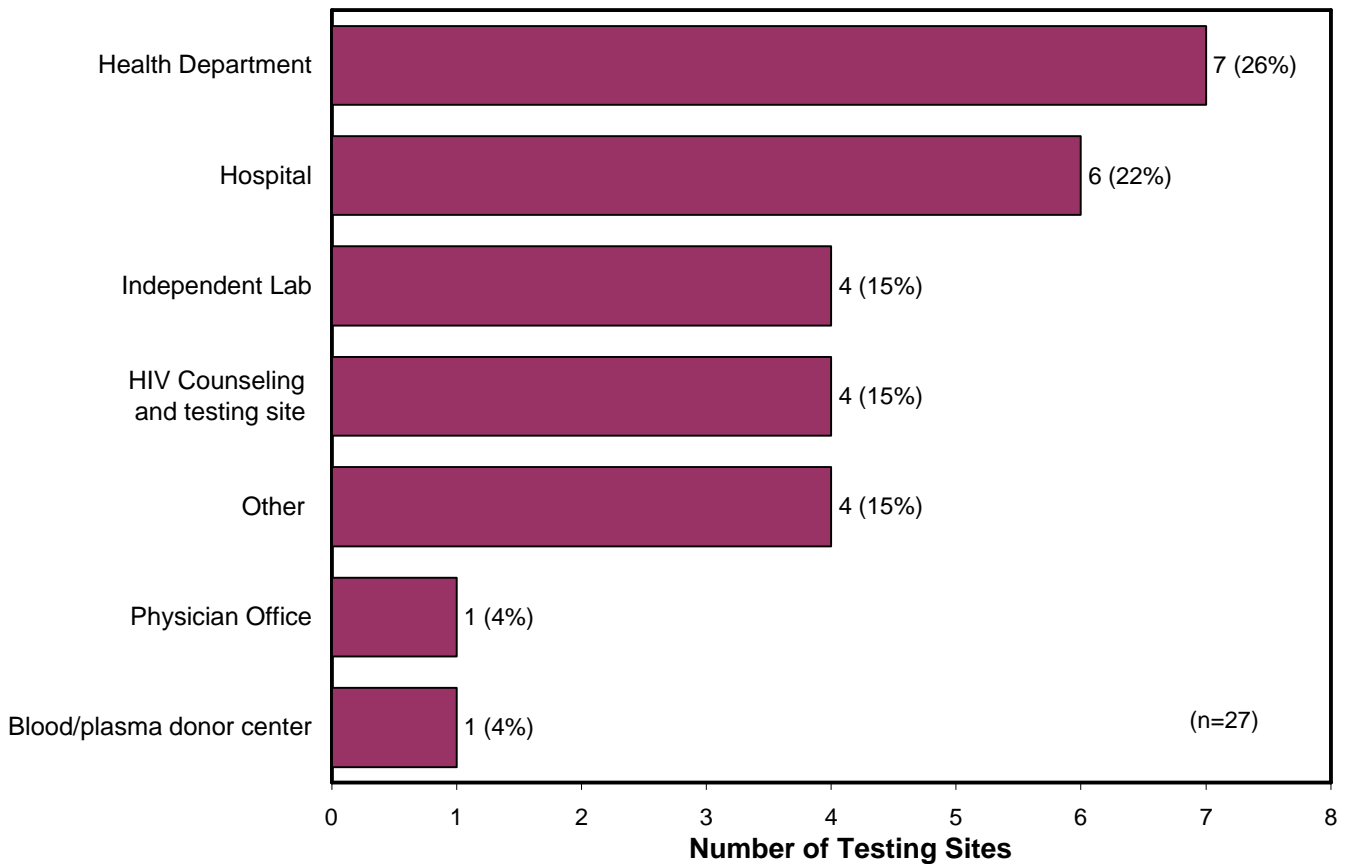
Note: Use of trade names is for identification only and does not imply endorsement by the Centers for Disease Control and Prevention.

1.(a) Please indicate the primary classification of your facility/testing site. (Check one primary classification.)

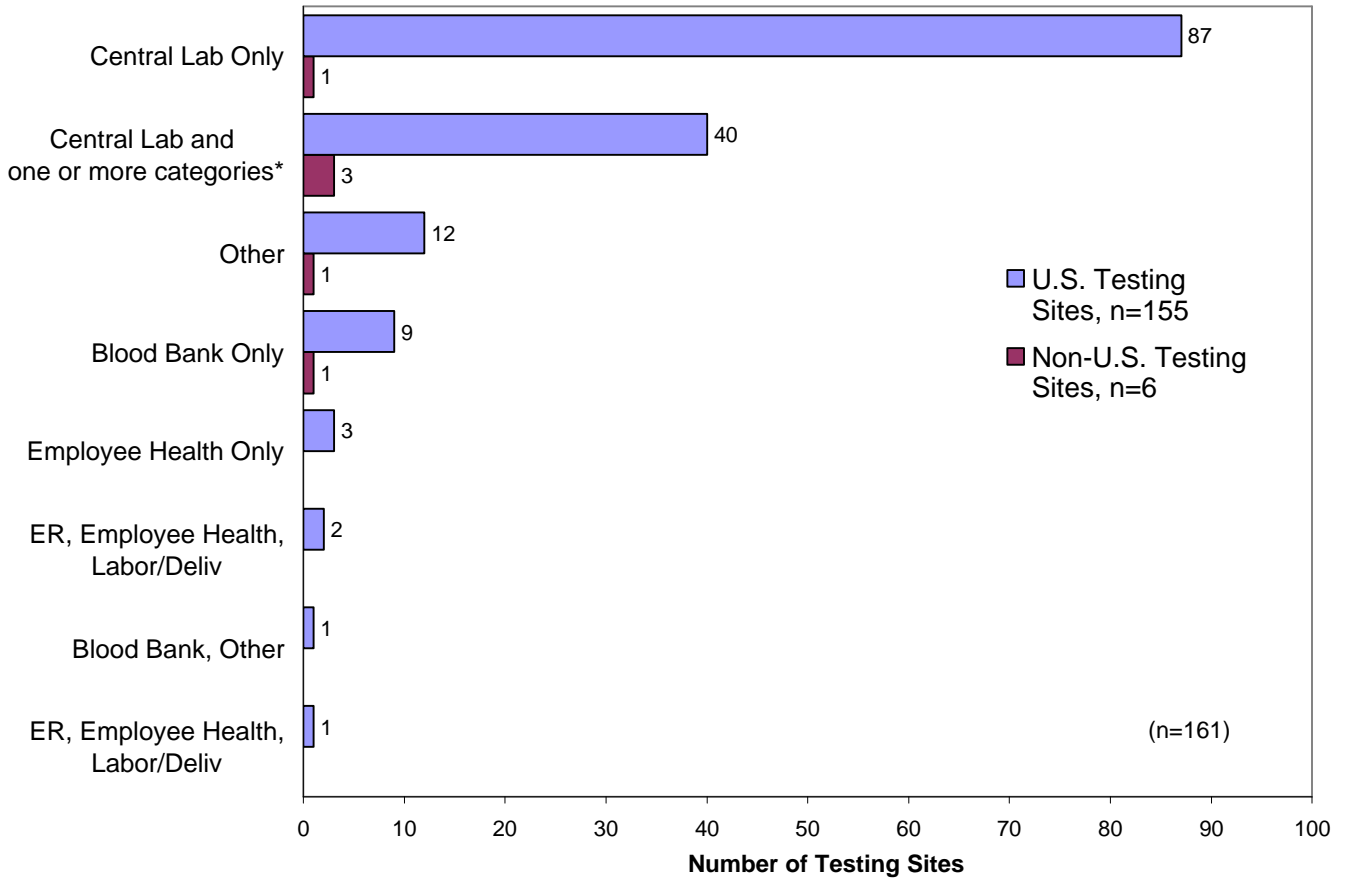
Primary Type of U.S. Testing Site



Primary Type of Non-U.S. Testing Site

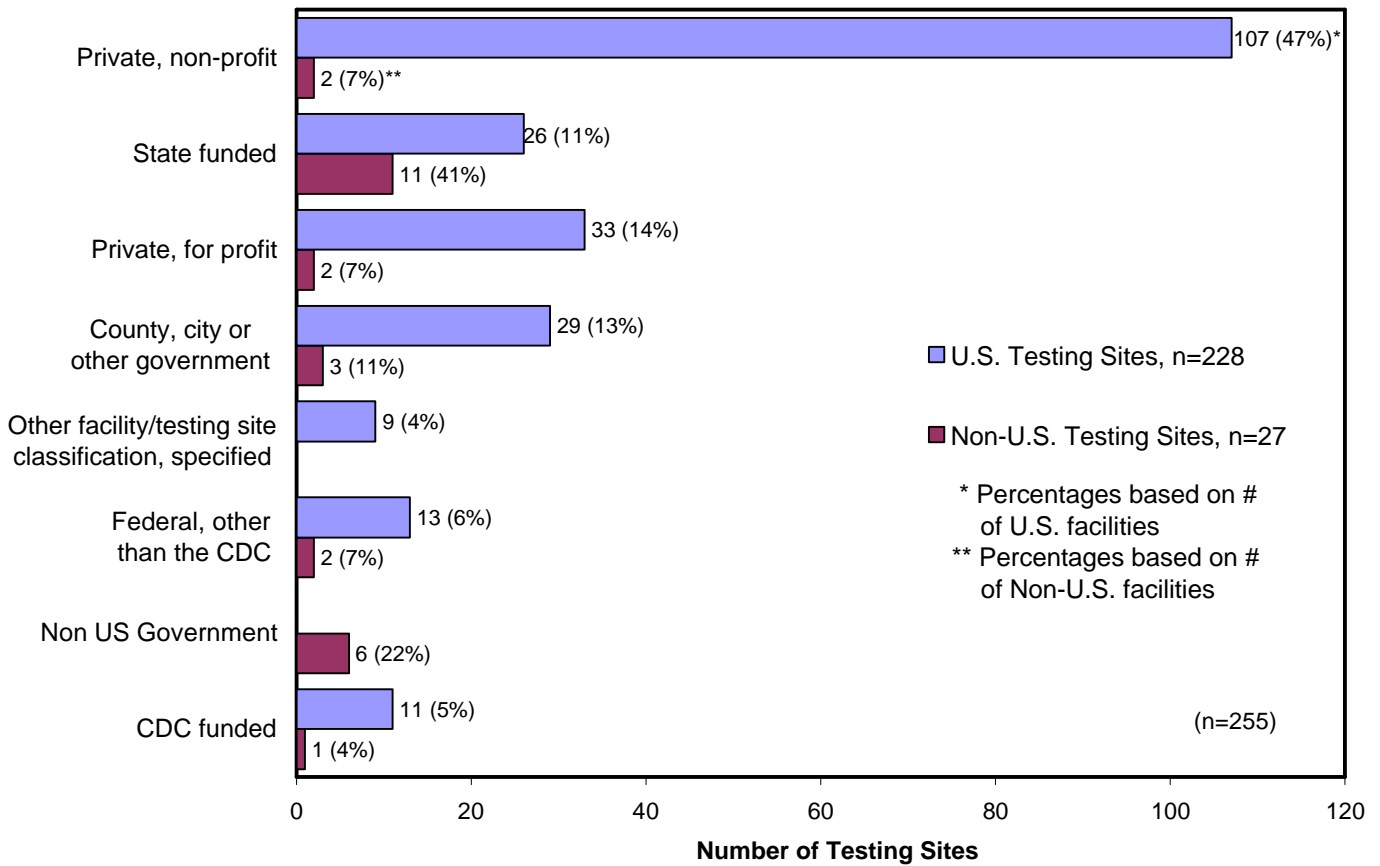


Testing Sites within Hospitals



* The "more categories" include: Hospital Admissions, Emergency Room (ER), Blood Bank, Employee Health, Hospital Ward, Labor/Delivery, and "Other" hospital testing sites.

1.(b) Who PRIMARILY funds your testing site? (Check only ONE BEST answer)



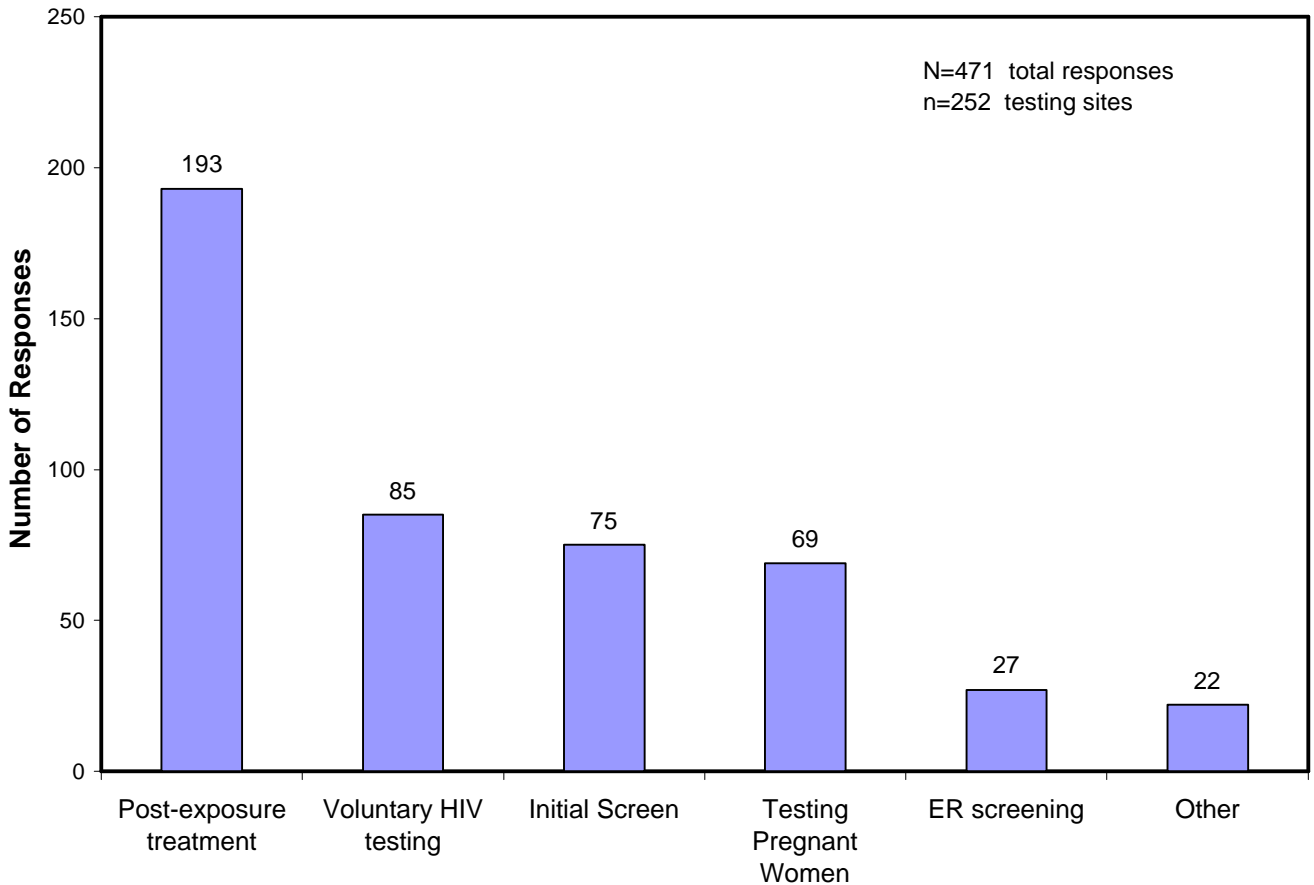
2.(a) Does your facility currently perform HIV rapid testing?

Response	Number of Facilities (%) (n=263)
Yes	253 (96%)
No	10 (4%)

2.(b) Does your facility intend to begin performing HIV rapid testing? (Choose only one.)

Response	Number of Facilities (%) (n=10)
Within 6 months	3 (30%)
Yes, unsure when	2 (20%)
No	4 (40%)
Not Specified	1 (10%)

3.(a) For what purpose(s) do you offer HIV rapid testing? (Check all that apply.)

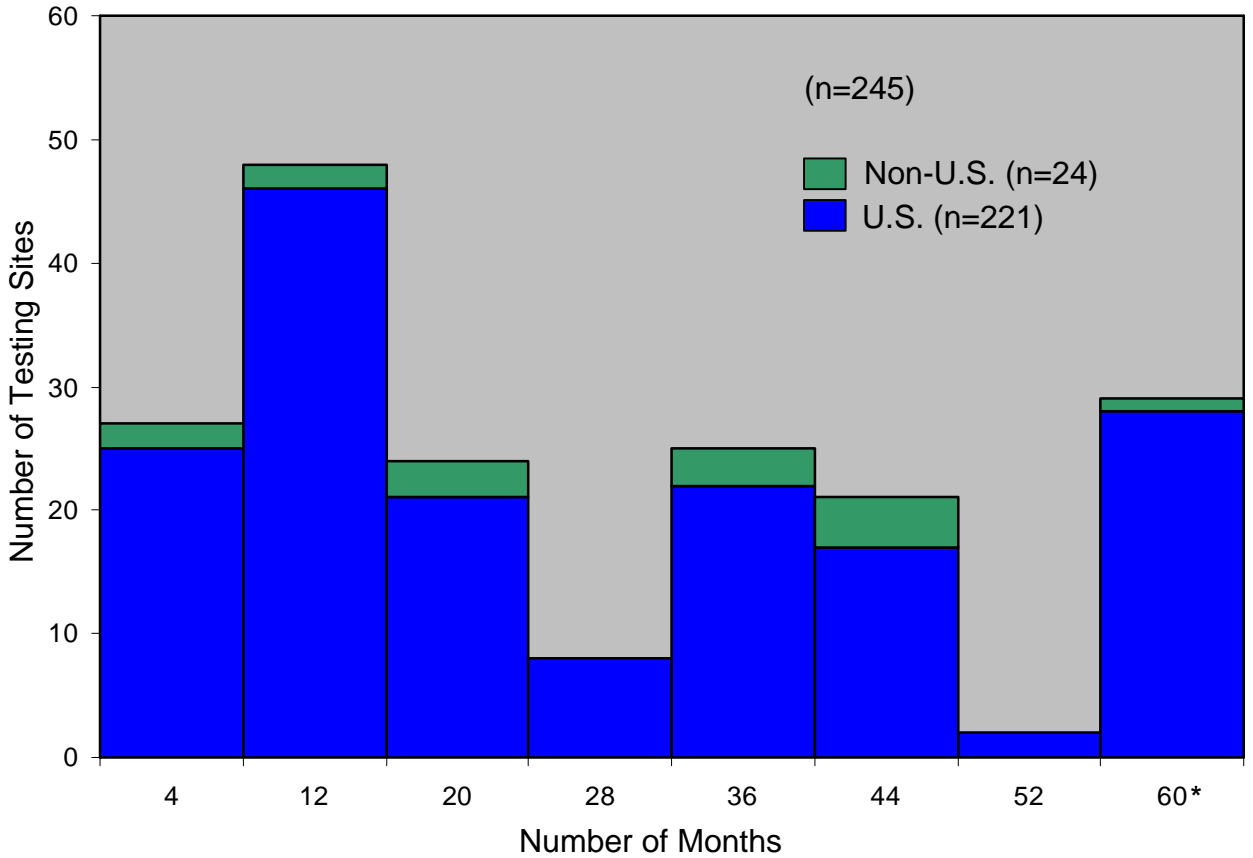


Note: Facilities could submit more than one answer.

Nearly half (43%, 108/252) of the participants that answered the question included one or both of the categories “voluntary testing” and/or “initial screening”. The percents of each facility type that indicated one or both categories are listed below.

- hospitals: 24% (39/164),
- health departments: 88% (28/32),
- physicians office: 71% (10/14),
- community-based organization (CBO): 82% (9/11),
- counseling and testing sites: 88% (7/8)
- other testing sites: 100% (5/5)
- independent sites: 30% (3/10)
- family planning centers: 100% (2/2),
- STD clinics: 100% (2/2), and
- blood/plasma donor center, drug treatment center, health management organization (HMO), and mobile unit: 75% (3/4).

3.(b) How long has your facility performed HIV rapid testing? (Please round off to the nearest whole number.)

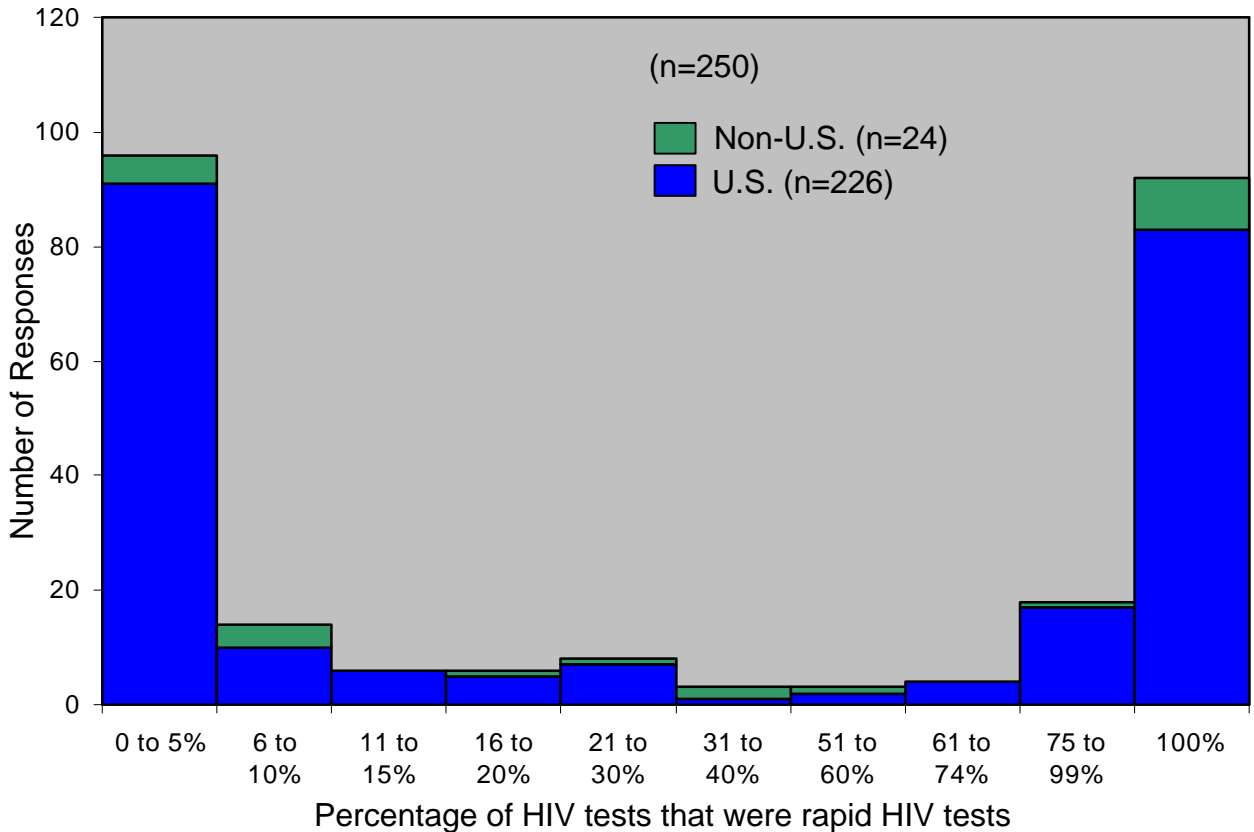


* Facilities responding ≥ 65 :

52 U.S. facilities responded ≥ 65

9 Non-U.S. facilities responded ≥ 65

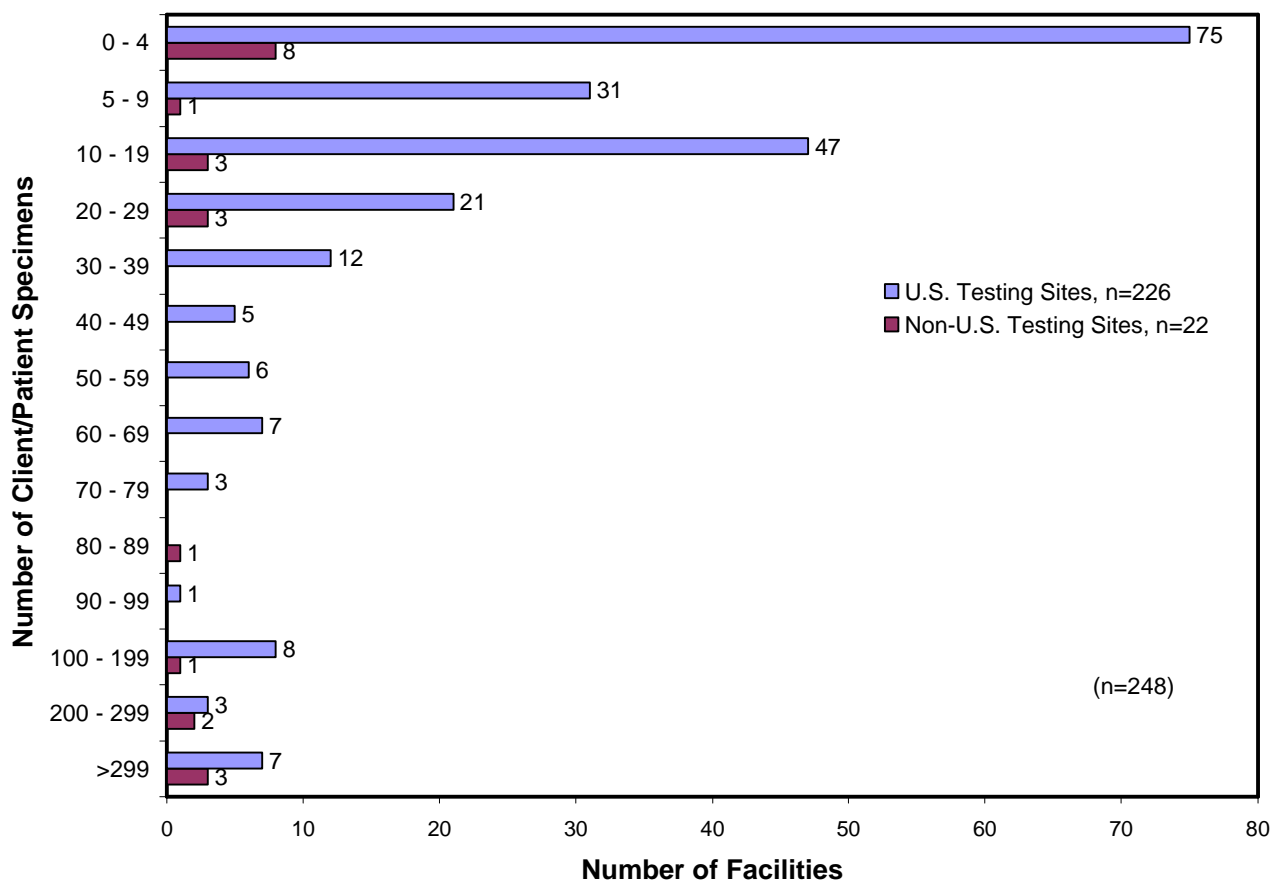
(c) Of all HIV testing performed in your facility over the past year, what percentage was performed using HIV rapid test kits? (Please round off to the nearest whole percentage.)



The graph of the data for this question appears bimodal, with most responses being either less than or equal to 10% or 100%. The facility types that gave responses primarily in one of these categories are listed below.

Facility type	Percent of HIV testing performed using HIV rapid test kits	
	<= 10 %	100%
Hospital	49% (81/167)	39% (65/167)
Health Department	39% (14/36)	19% (7/36)
Independent	67% (8/12)	17% (2/12)
Physician Office	7% (1/14)	50% (7/14)
CBO	27% (3/11)	36% (4/11)
Counseling & Testing Site		63% (5/8)
"Other"	20% (1/5)	20% (1/5)
Drug Treatment		100% (1/1)
HMO	100% (1/1)	
STD Clinic	100% (1/1)	

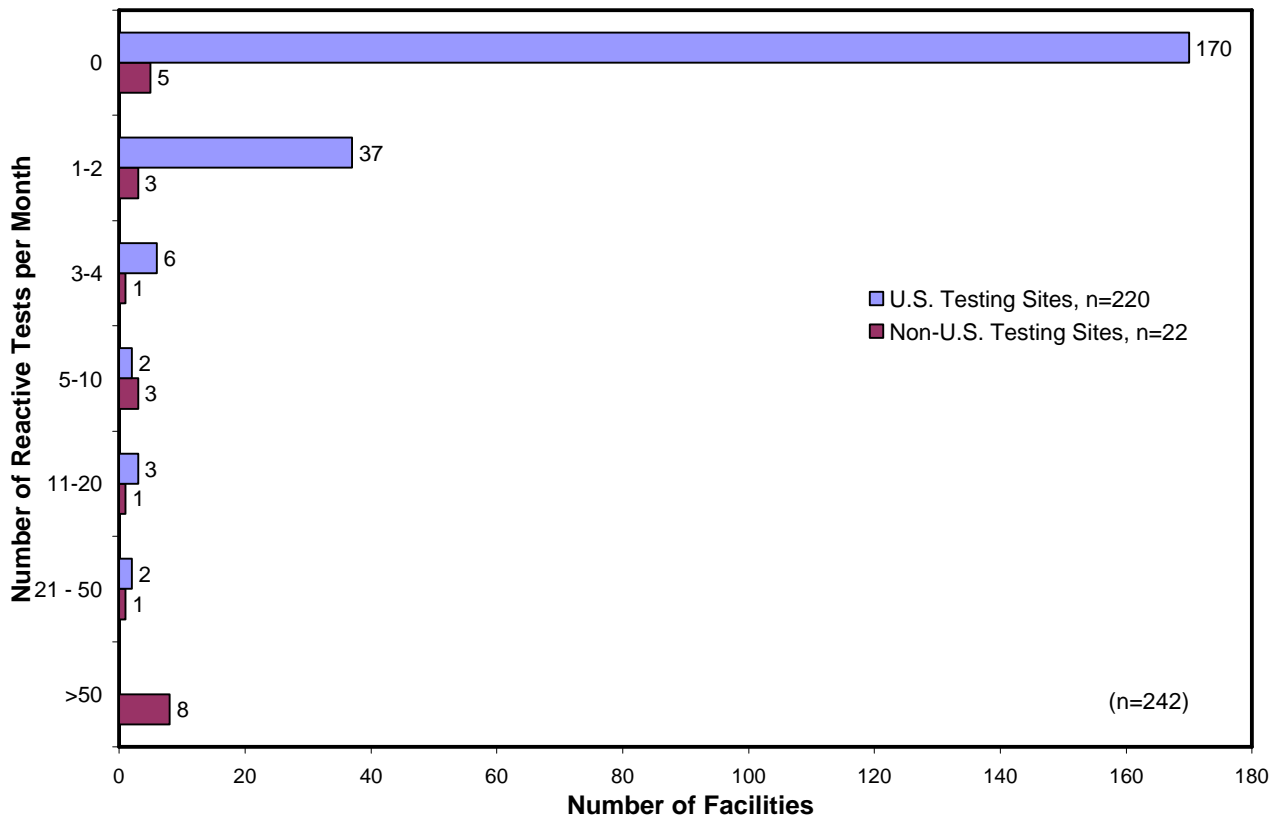
3.(d) How many client/patient specimens were tested using HIV rapid tests in your facility during the most recent representative month? (Please round off to the nearest whole number.)



- The graph of the data for this question appears bimodal; with most responses being either ≤ 30 specimens or ≥ 200 specimens tested using HIV rapid tests (RT).
- All facilities that perform >299 tests/representative month gave responses that indicated they use HIV rapid testing for purposes which include initial screening and/or voluntary testing purposes.

Facility type	Number of Specimens Tested in the Most Recent Month	
	10 or more HIV RT/representative month	≥ 200 HIV RT/representative month
Hospital	44% (73/167)	1% (2/167)
Health Department	58% (21/36)	17% (6/36)
Independent	50% (6/12)	
Physician Office	79% (11/14)	
CBO	55% (6/11)	9% (1/11)
“Other”	40% (2/5)	
Drug Treatment Center, Mobile Unit, STD Clinic, Counseling & Testing Site	100% (12/12)	42% (5/12)
Family Planning	25% (1/4)	
Blood/Plasma Donor Center	100% (1/1)	100% (1/1)

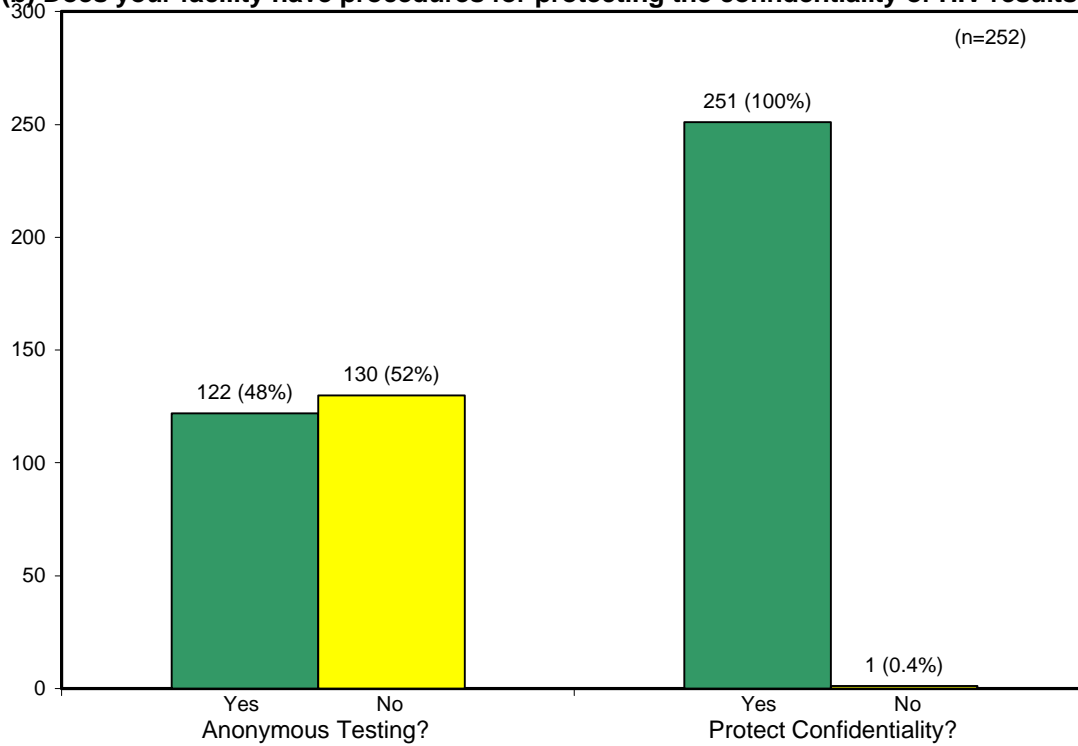
(e) Of the specimens reported in 3(d) above, how many were initially reactive (preliminary positive) during the same most recent representative month? (Please round off to the nearest whole number.)



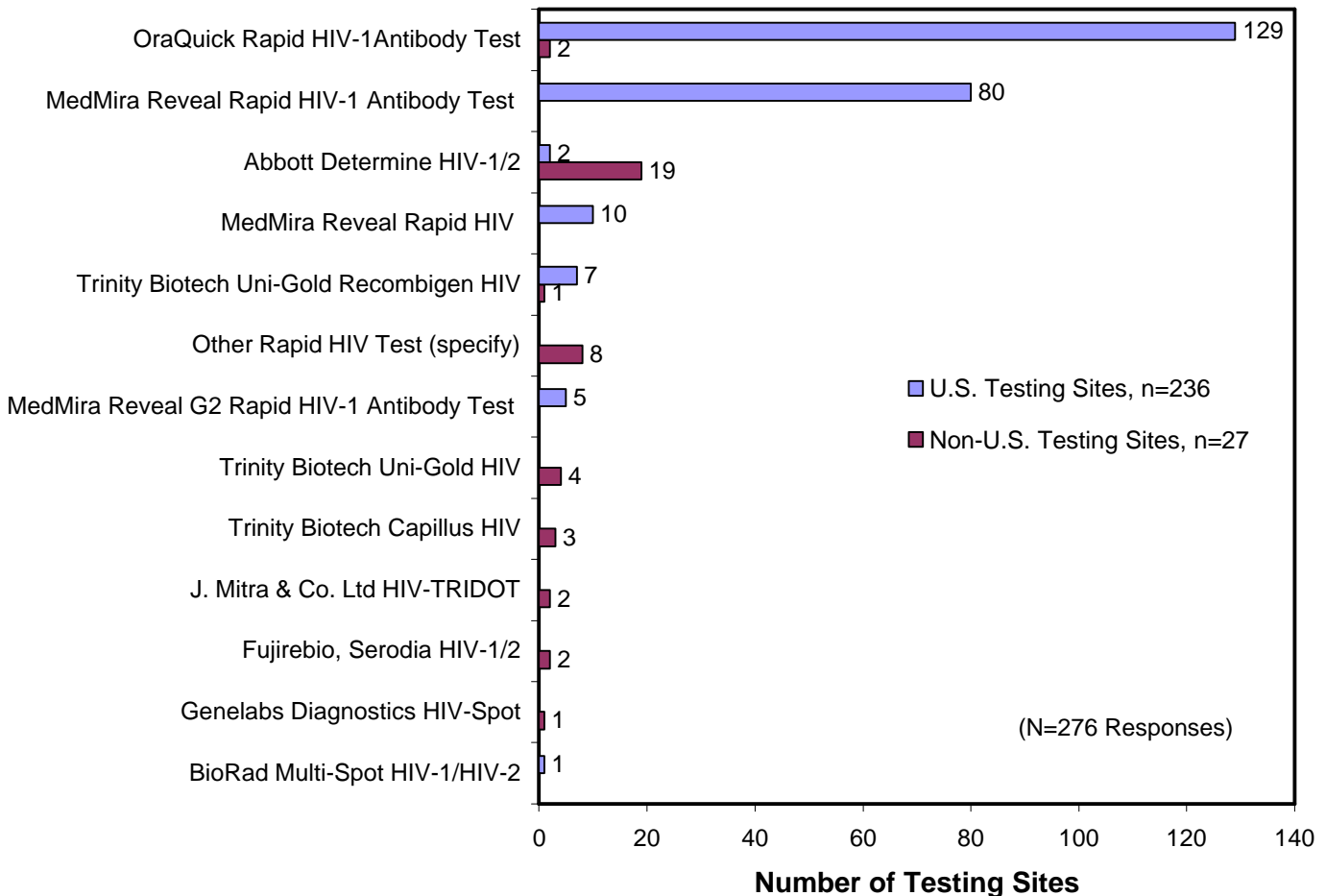
- Of the 175 labs that reported 0 positive HIVRT in the most recent representative month, 78% (137/175) performed less than 20 tests in that month.
- The facility types that had ≥ 1 initially reactive (preliminary positive) HIV rapid test in the most recent representative month are listed below, by number and percentage of sites responding to the survey.
 - Hospitals: (19%, 31/167)
 - Health departments: 36% (13/36)
 - Counseling and Testing sites: 100% (8/8)
 - Physician Office: 29% (4/14)
 - Independent facilities: 25% (3/12)
 - STD Clinic: 100% (2/2)
 - CBO: 18% (2/11)
 - “Other”: 40% (2/5)
 - Mobile Units: 100% (1/1)
 - Blood/Plasma Center: 100% (1/1)

4.(a) Does your facility provide anonymous HIV rapid testing?

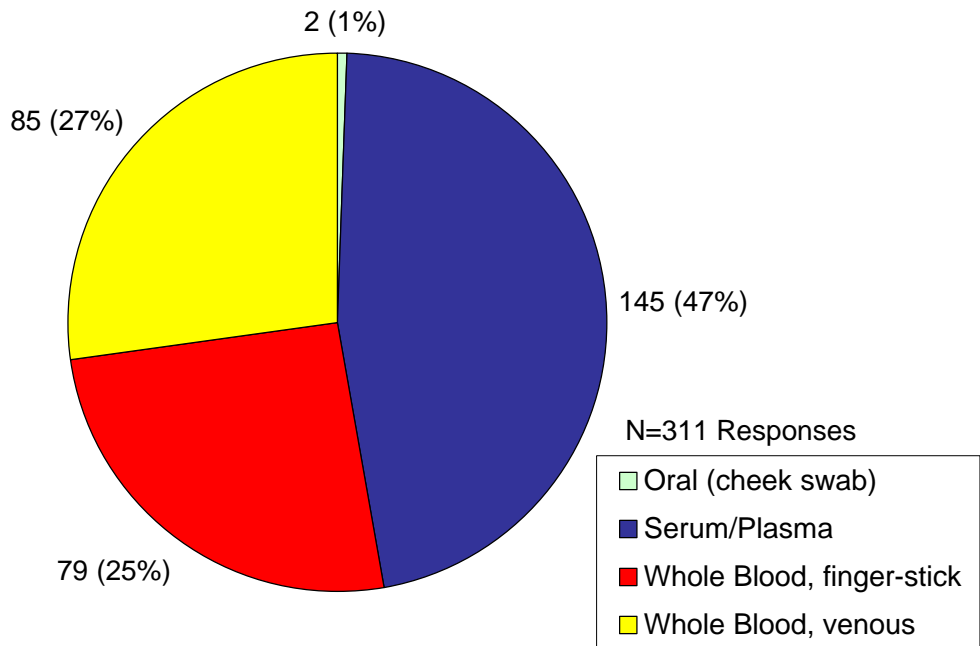
(b) Does your facility have procedures for protecting the confidentiality of HIV results?



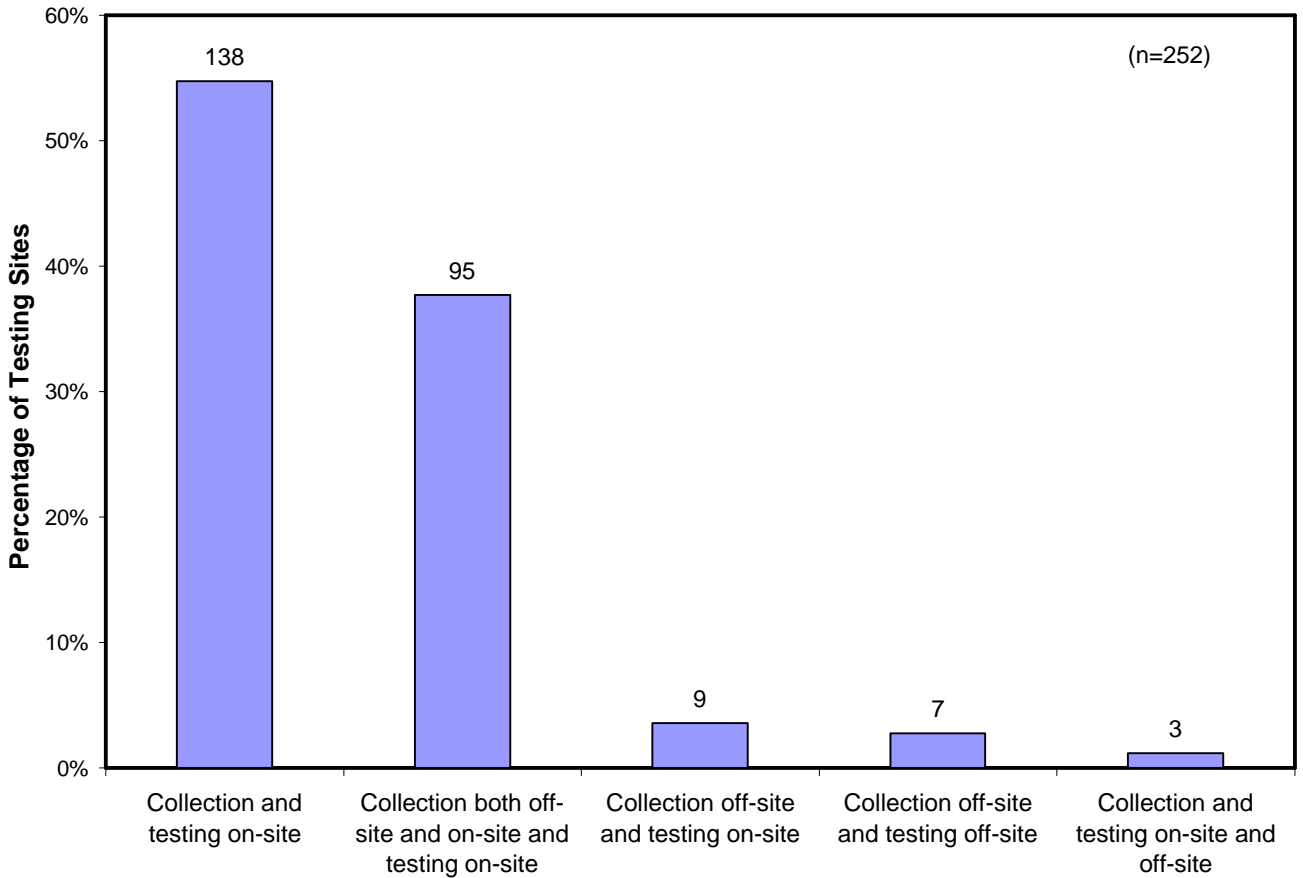
5. What test kit(s) do you currently use for HIV rapid testing? (Check all that apply.)



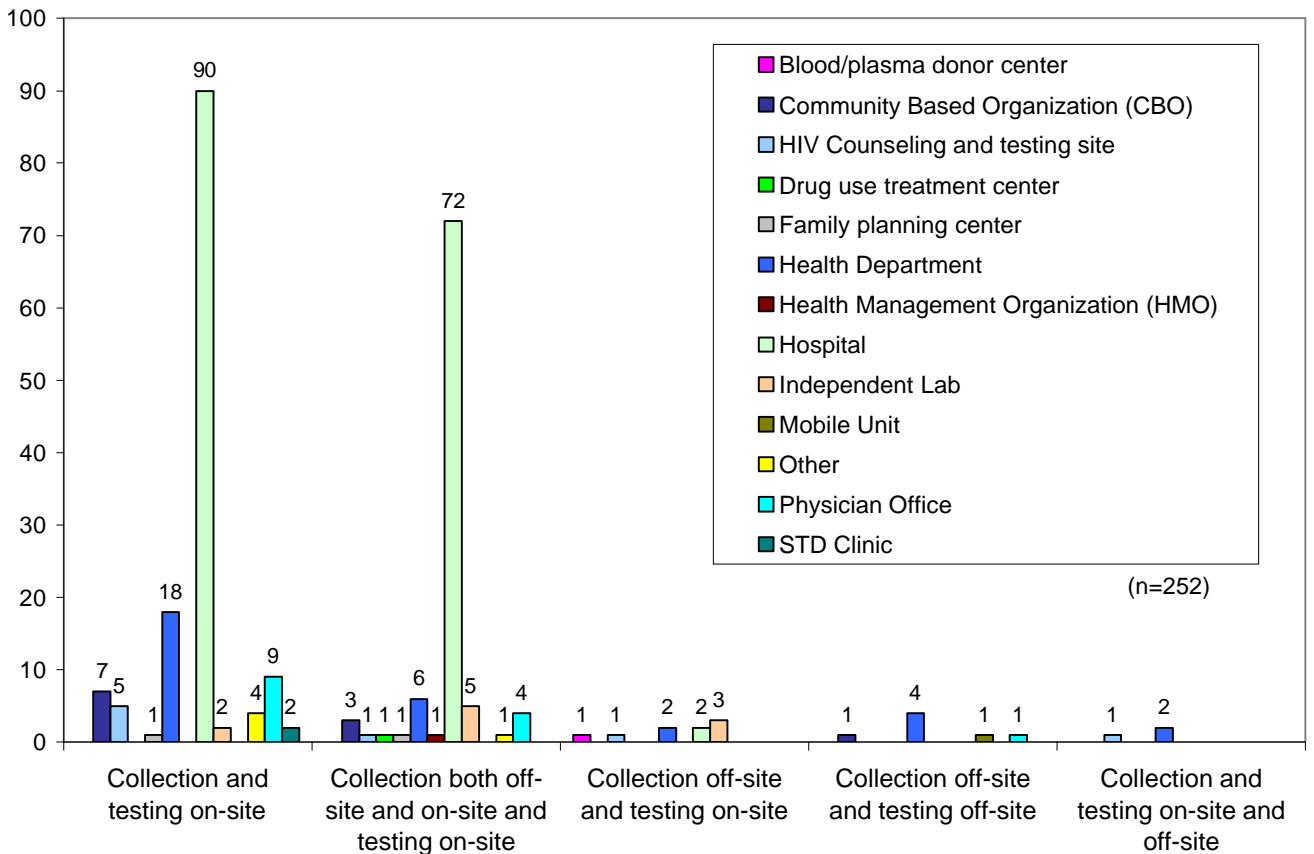
6. What sample type do you currently use for HIV rapid testing? (Check all that apply.)



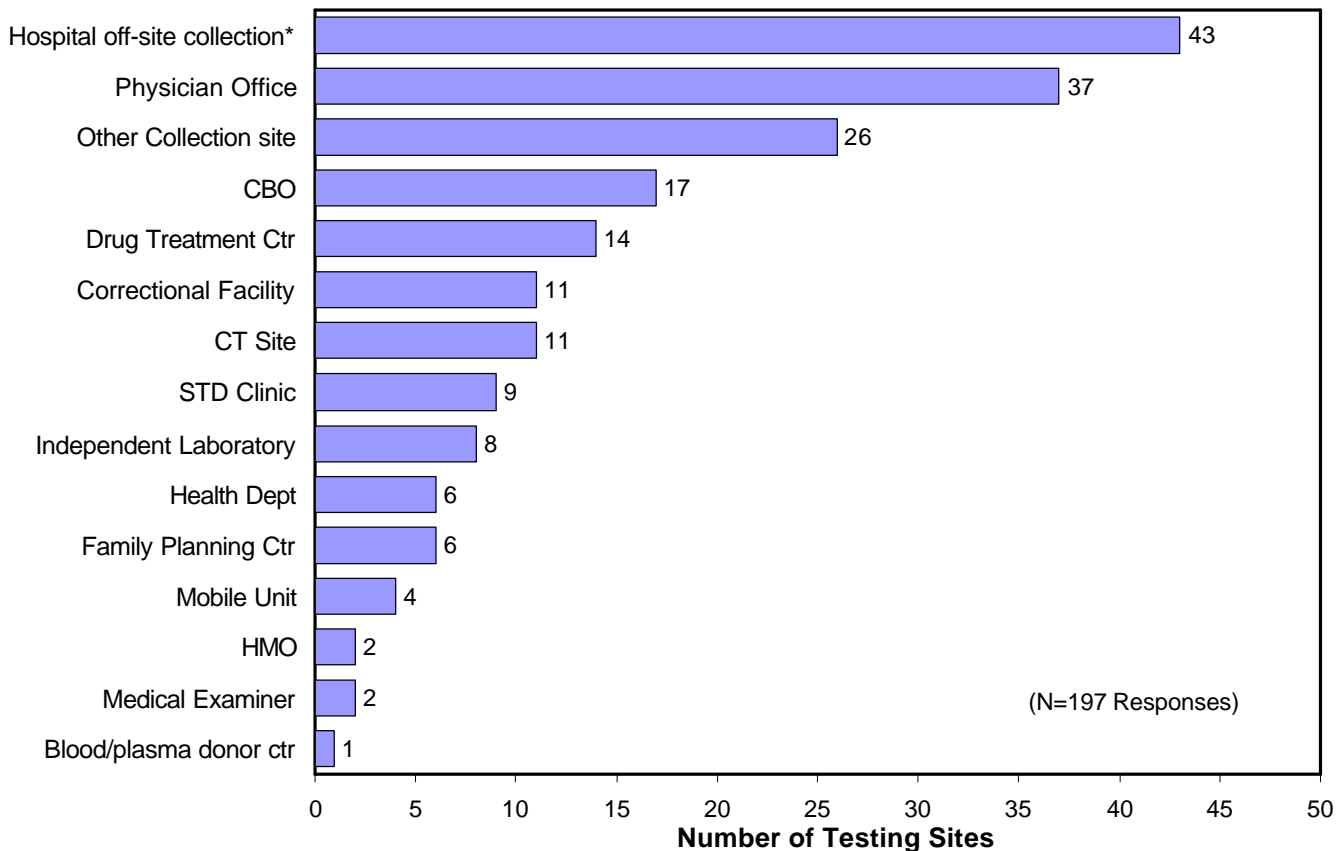
7.(a) Where are specimens collected and HIV rapid testing performed? (Choose only one.)



7.(a) Specimen collection site and testing site by lab type



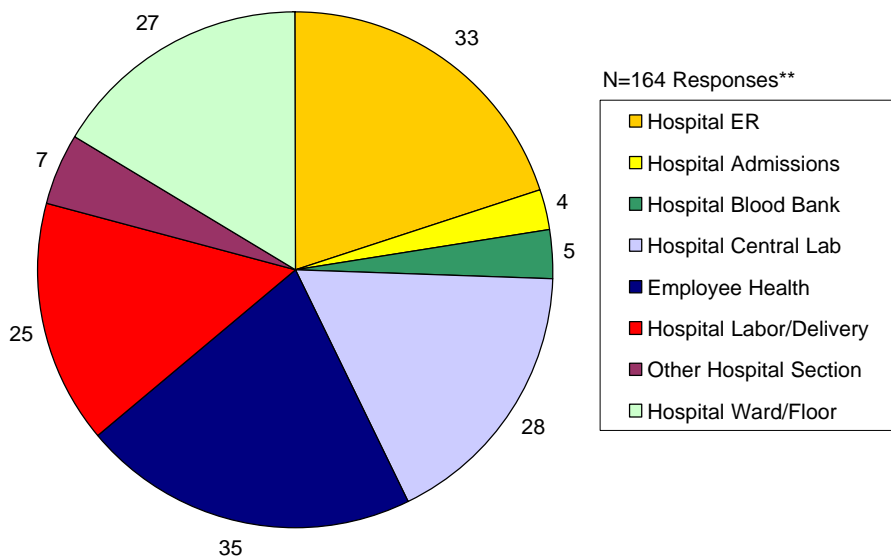
7.(b) If you perform HIV rapid testing on specimens collected off-site, please indicate where they are collected. (Check all that apply.)



Of the “other” off-site collections:

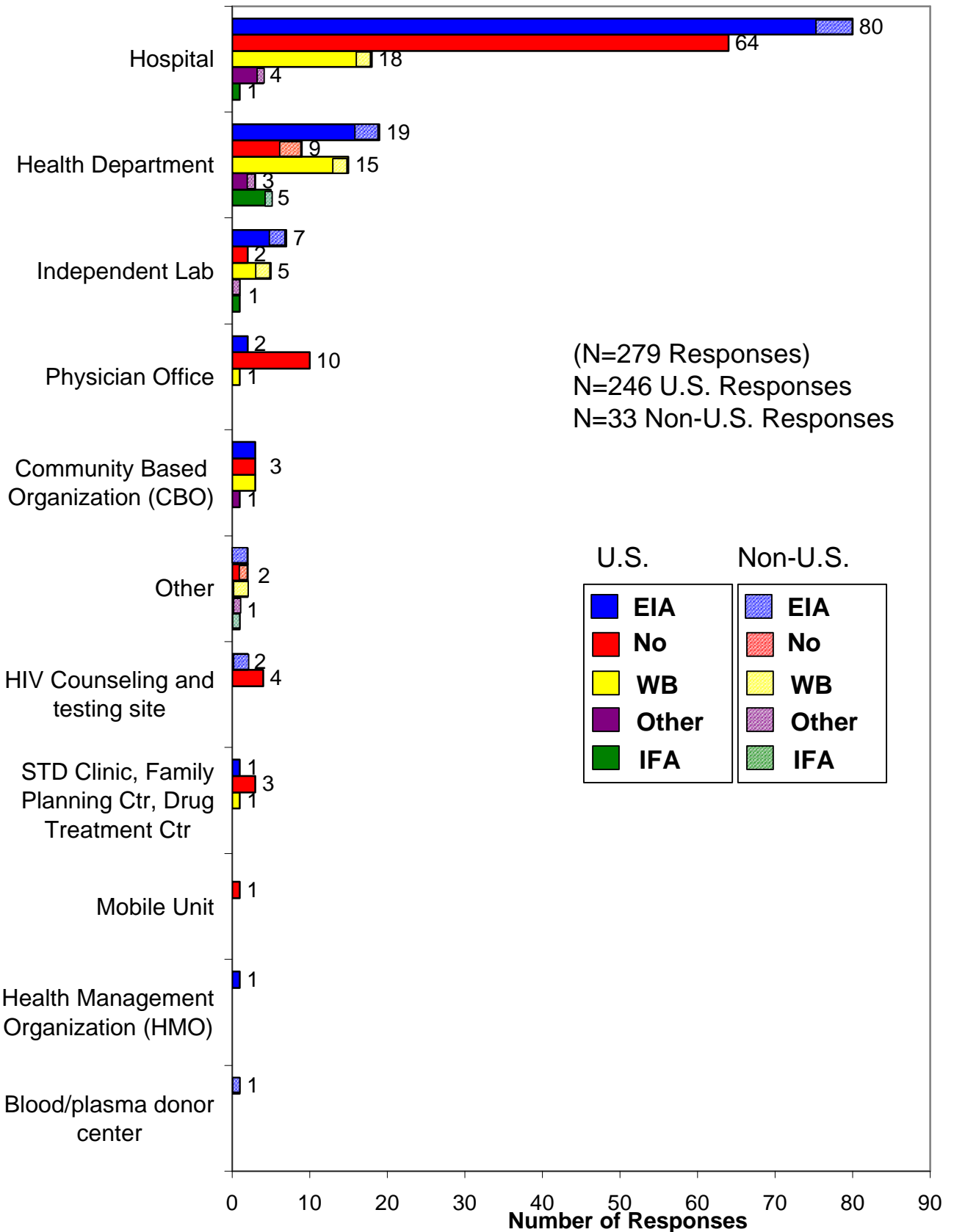
- 10/26 were nursing homes or outreach/home health care sites,
- 3/26 were outpatient surgery sites,
- 2/26 were immediate/urgent care sites, and
- 4/26 were satellite sites of the main facility.

*** Specific Hospital Collection Sites (Check all that apply.)**



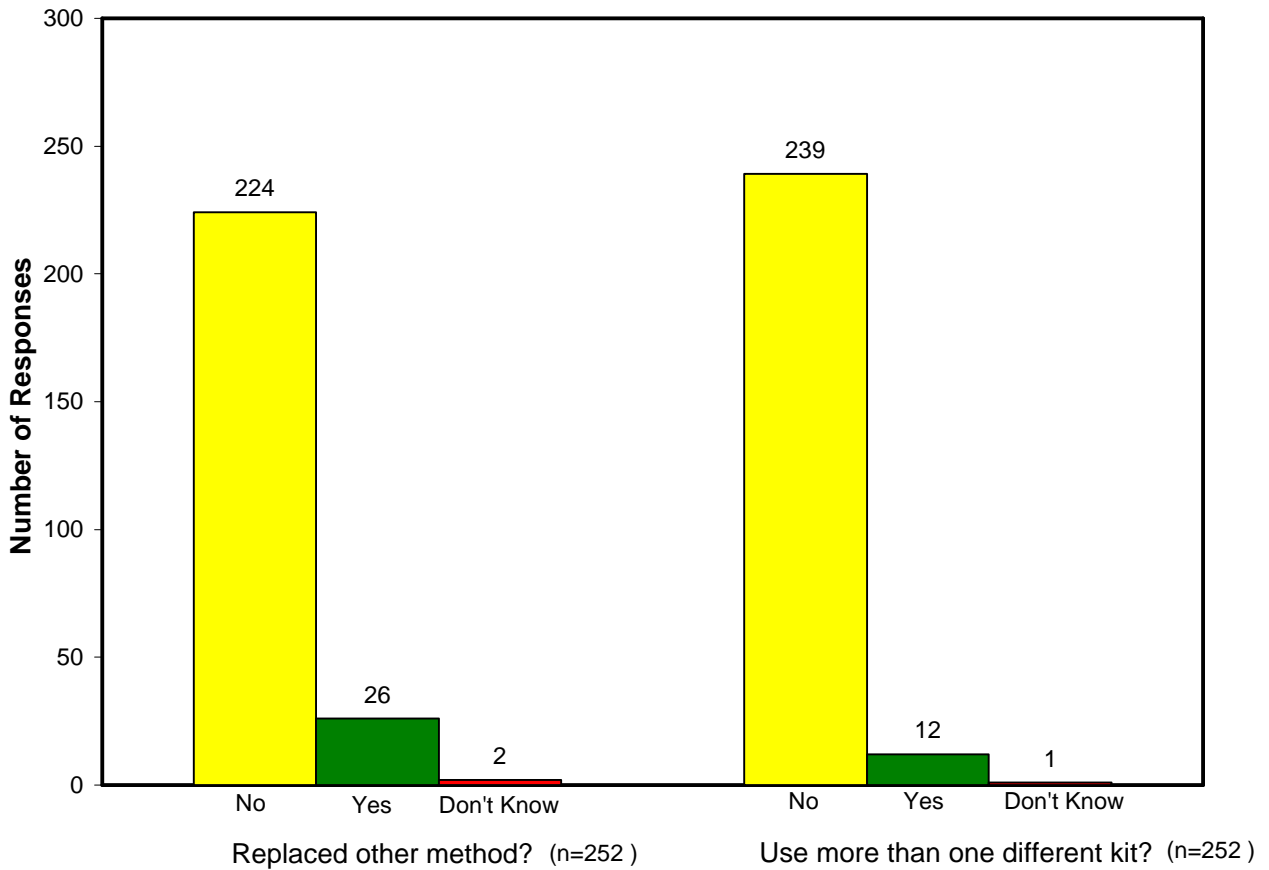
** This represents multiple responses from hospital participants

8. To detect HIV infection, do you currently perform a test in your facility other than an HIV rapid test? (If yes, check all that apply.)



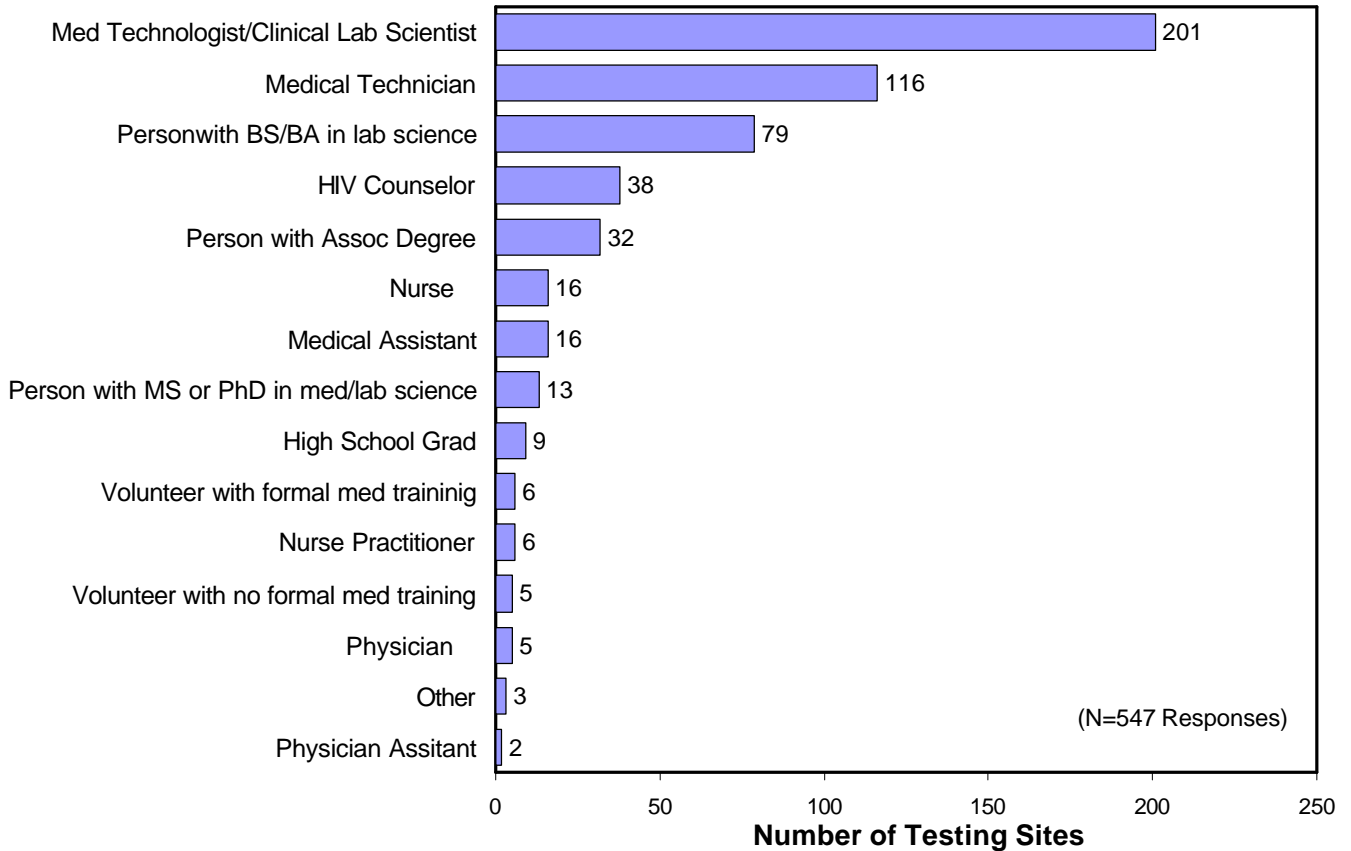
9(a). Has HIV rapid testing replaced some other method of HIV testing?

9(b). Do you perform HIV rapid testing using more than one different test kit?



- Of the 26 facilities that specified HIV RT replaced some “other” test,
 - 14 of those replaced were specified as EIA methods,
 - 7 methods replaced were identified as an oral testing method (e.g. the OraSure oral swab/Western blot),
 - 4 were unspecified HIV tests that were performed at another facility, and
 - 1 did not specify the method.

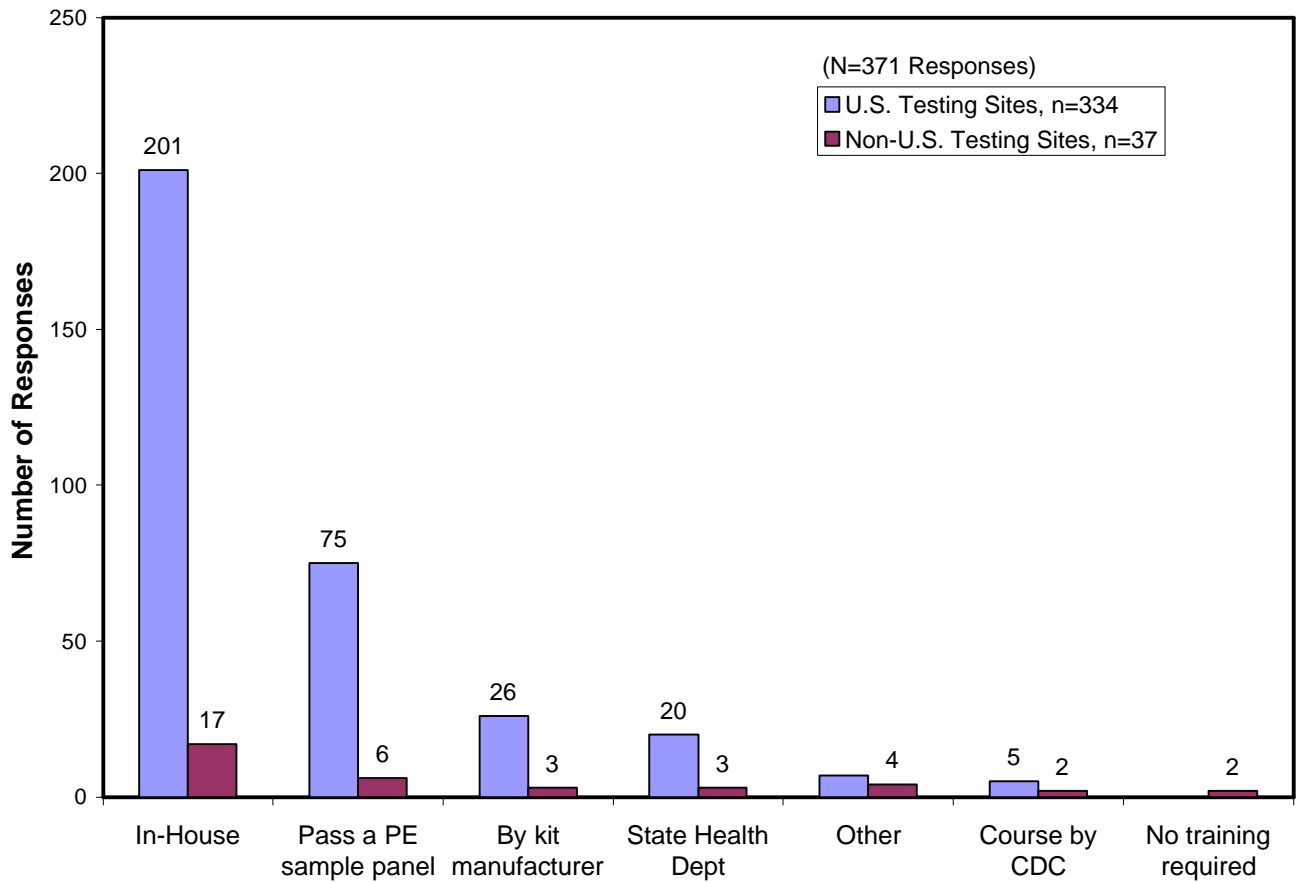
10. Who performs HIV rapid testing in your facility on a regular basis? (Check all that apply.)



The majority (78%, 375/480) of responses from hospitals, health departments, physician offices and facilities identified as “independent” primarily indicated that the personnel who performed HIV rapid testing in their facility were medical technicians, medical technologists, or someone with a BA/BS degree in a relevant field (e.g. laboratory science, biology, etc.). A summary by facility type is below.

- Hospital: 88% (298/337 responses),
- Health Department: 46% (36/78 responses),
- Physician Office: 56% (19/34), and
- Independent: 71% (22/31).

11. What type of training is required for personnel performing HIV rapid testing in your facility/testing site? (Check all that apply)



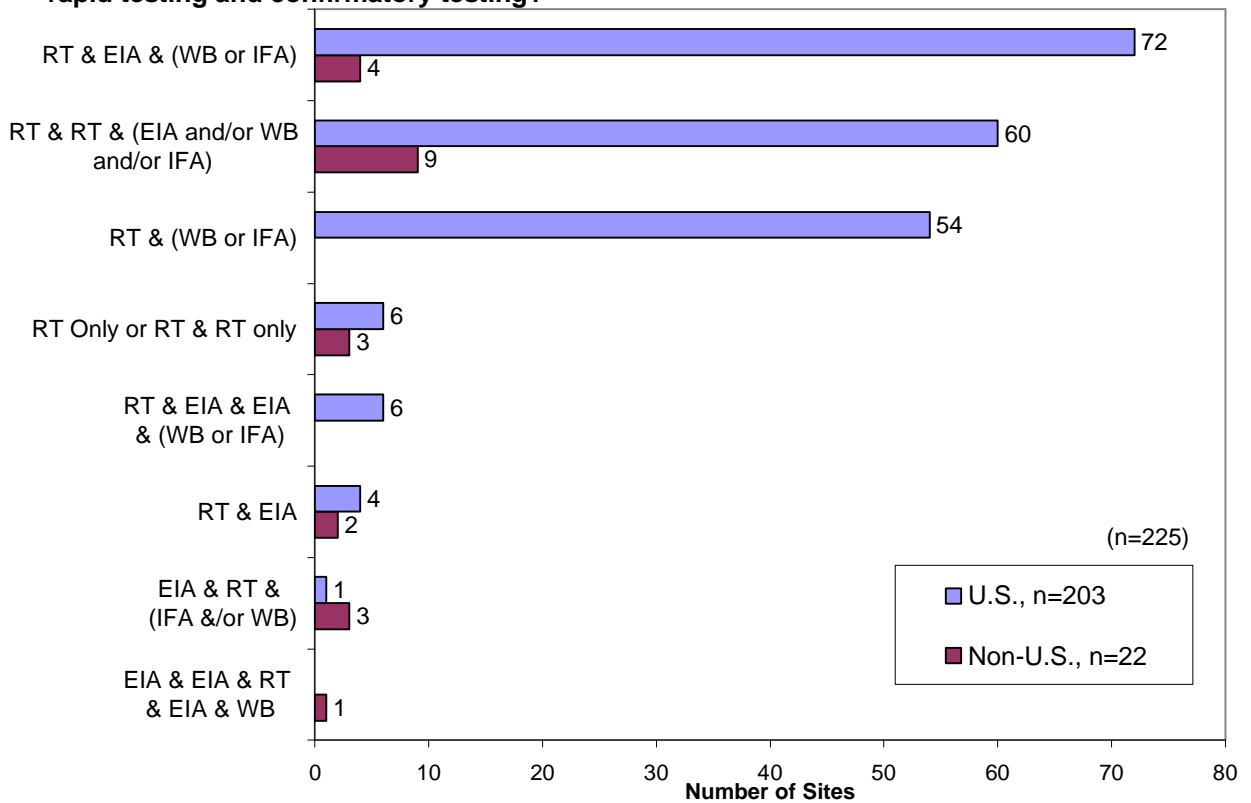
11. (Continued) Length of training by type of training

Training Type	# of Responses (N=)	Range	Median
In-house	194	0-160 hours	1 hours
Sample Panel Evaluation	74	1-25 samples	5
By Kit Manufacturer	27	0-24 hours	2 hours
Health Department	24	4-40 hours	9 hours
CDC	8	16-56 hours	24 hours

12.(a) Is confirmatory testing performed (either in your facility or another facility) on initially reactive (preliminary positive) HIV rapid tests?

Facility Type	Yes	No	Total
Hospital	158 (96%)	6 (4%)	164 (65%)
Health Department	32 (100%)		32 (13%)
Physician Office	13 (93%)	1 (7%)	14 (6%)
Community Based Organization (CBO)	9 (82%)	2 (18%)	11 (4%)
Independent Lab	10 (100%)		10 (4%)
HIV Counseling and testing site	8 (100%)		8 (3%)
Other primary classification, specified	4 (80%)	1 (20%)	5 (2%)
Family planning center	2 (100%)		2 (1%)
STD Clinic	2 (100%)		2 (1%)
Blood/plasma donor center		1 (100%)	1 (0.4%)
Drug use treatment center	1 (100%)		1 (0.4%)
Health Management Organization (HMO)	1 (100%)		1 (0.4%)
Mobile Unit	1 (100%)		1 (0.4%)
Total	241 (96%)	11 (4%)	252 (100%)

12.(b) What is the typical algorithm, or order of tests, you use in your laboratory/testing site for HIV rapid testing and confirmatory testing?



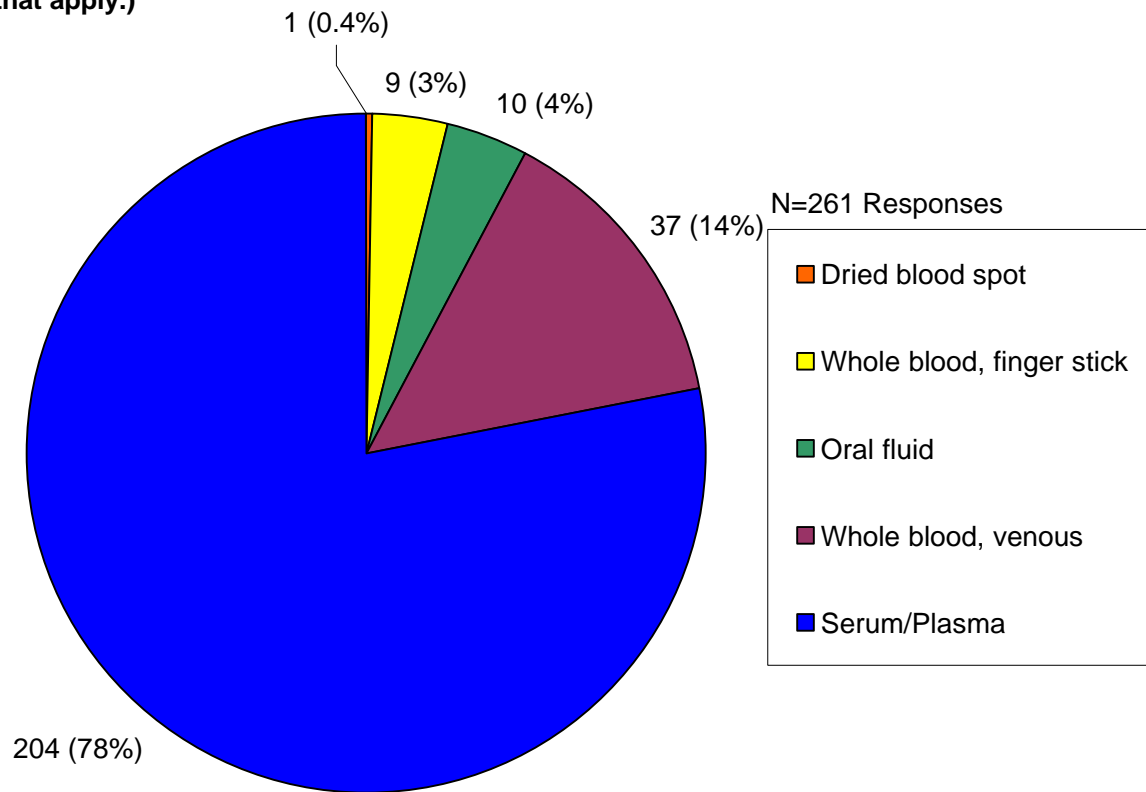
Algorithms for HIV Rapid Testing

n=225

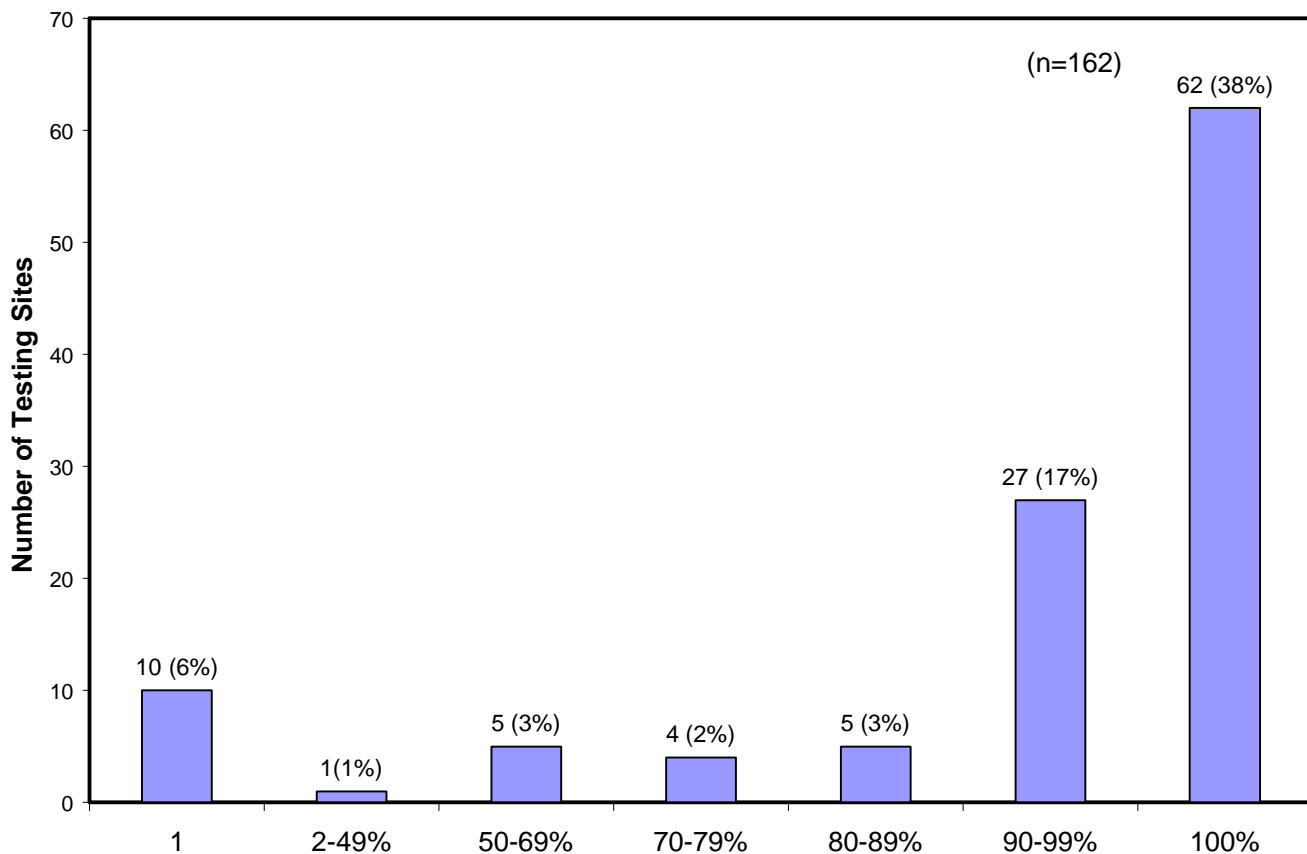
Step 1	Step 2	Step 3	Step 4	Step 5	Number of Laboratories	Percentage of Laboratories
RT	EIA	WB			66	29.3%
RT	WB				54	24.0%
RT	RT	WB			20	8.9%
RT	RT/RT	WB			17	7.6%
RT	RT	EIA	WB		15	6.7%
RT	RT/RT	EIA	WB		10	4.4%
RT	RT				7	3.1%
RT	EIA	EIA	WB		5	2.2%
RT	EIA				5	2.2%
EIA	RT	WB			4	1.8%
RT	EIA	IFA			4	1.8%
RT/RT	EIA	WB			3	1.3%
RT	RT	EIA			3	1.3%
RT					2	0.9%
RT	EIA	IFA	WB		2	0.9%
Other Algorithms					8	3.5%

Labels for Test: RT = HIV Rapid Testing, EIA = HIV-1 Enzyme Immunoassay, WB = HIV-1 Western Blot (WB), IFA = HIV-1 Indirect Immunofluorescence (IFA) RT/RT = 2 rapid HIV tests, done simultaneously

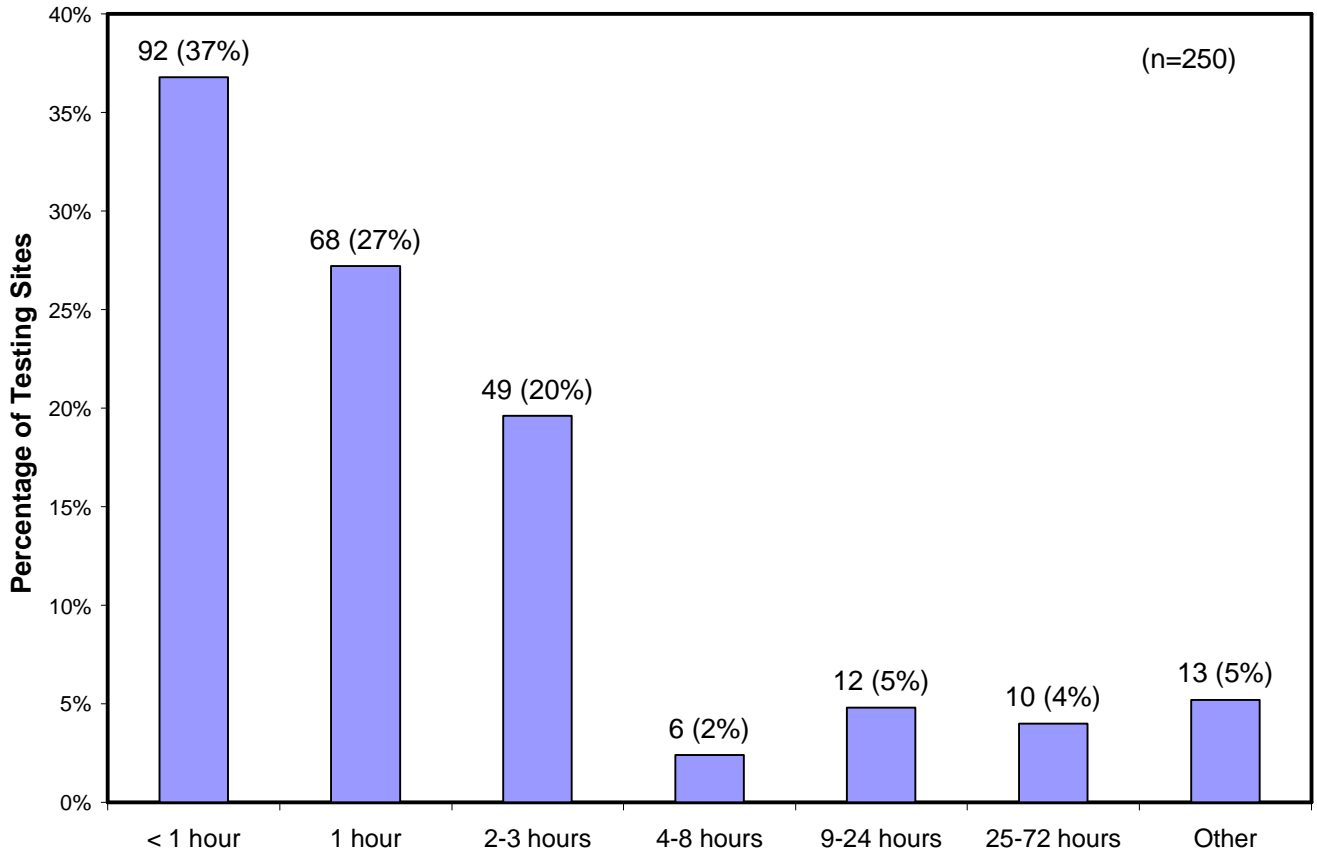
12.(c) What specimen type do you use to confirm initially reactive HIV rapid test results? (Check all that apply.)



12. (d) Of the initially reactive (preliminary positive) HIV rapid test results for which a confirmatory test was performed, what percentage was confirmed as positive? Please round off to the nearest whole percentage.)



13. On average, how much time passes from collection of the specimen for HIV rapid testing at your facility until results are reported (given) to the client/patient? (Check only one.)



- Of the 13 facilities that responded “other”:

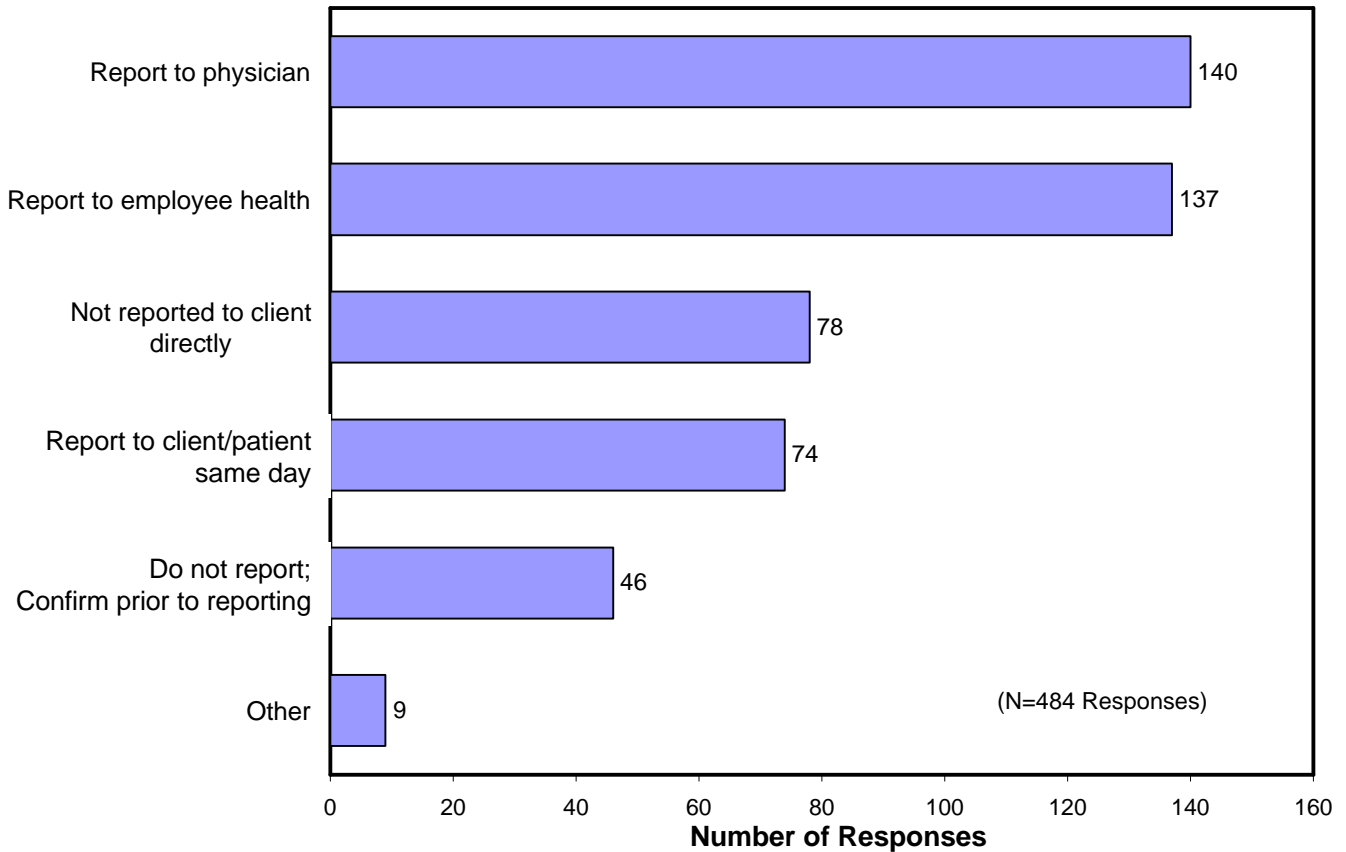
- eight answered that the time varied, of these

- four varied depending on if the specimen was a “stat” (urgent) or routine specimen,
- three varied depending on if the result was positive/initially reactive or negative/non-reactive, and
- one varied depending on the location of the collection site.

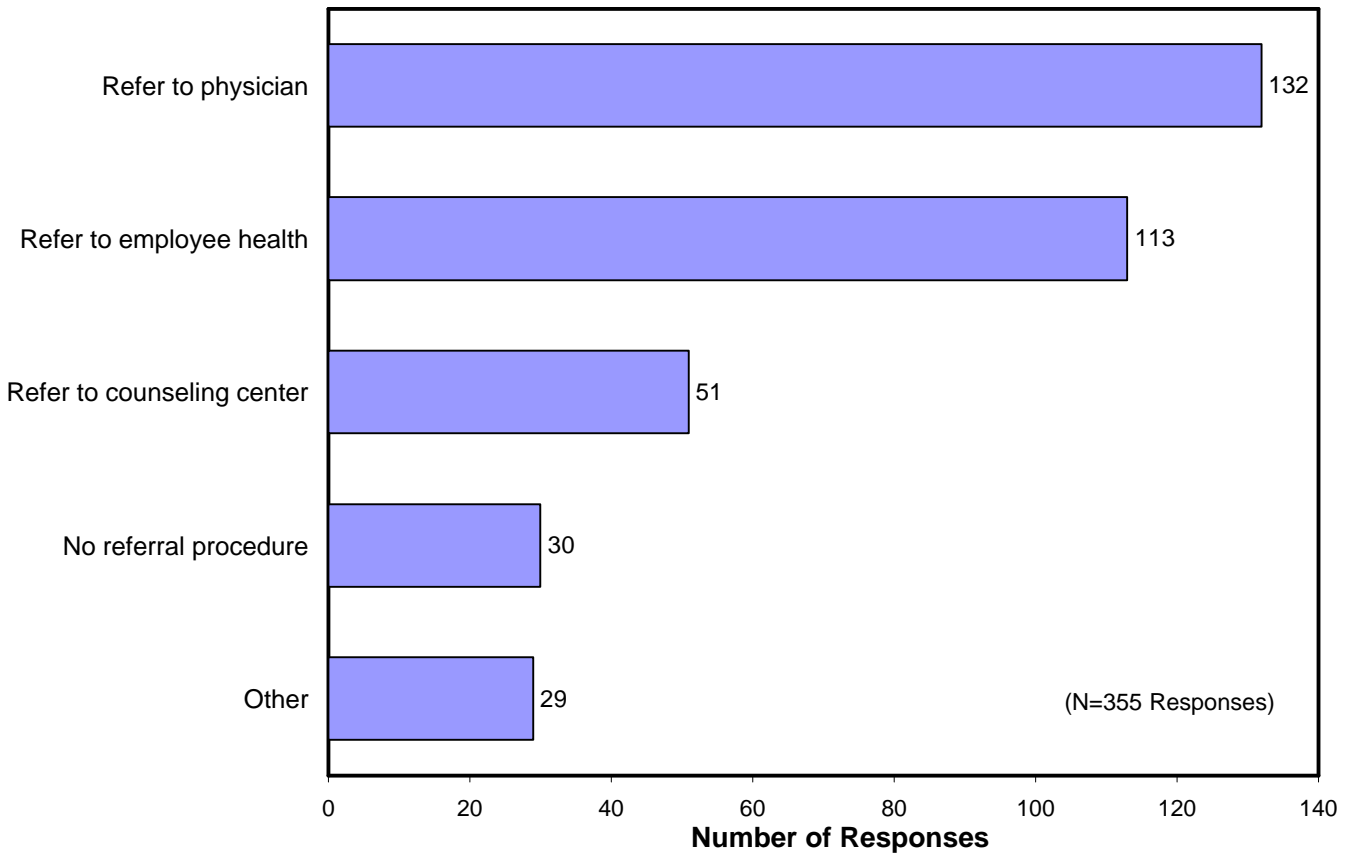
- three facilities answered “unknown” or commented that the result was referred.

- two facilities responded with times of between 5-7 days.

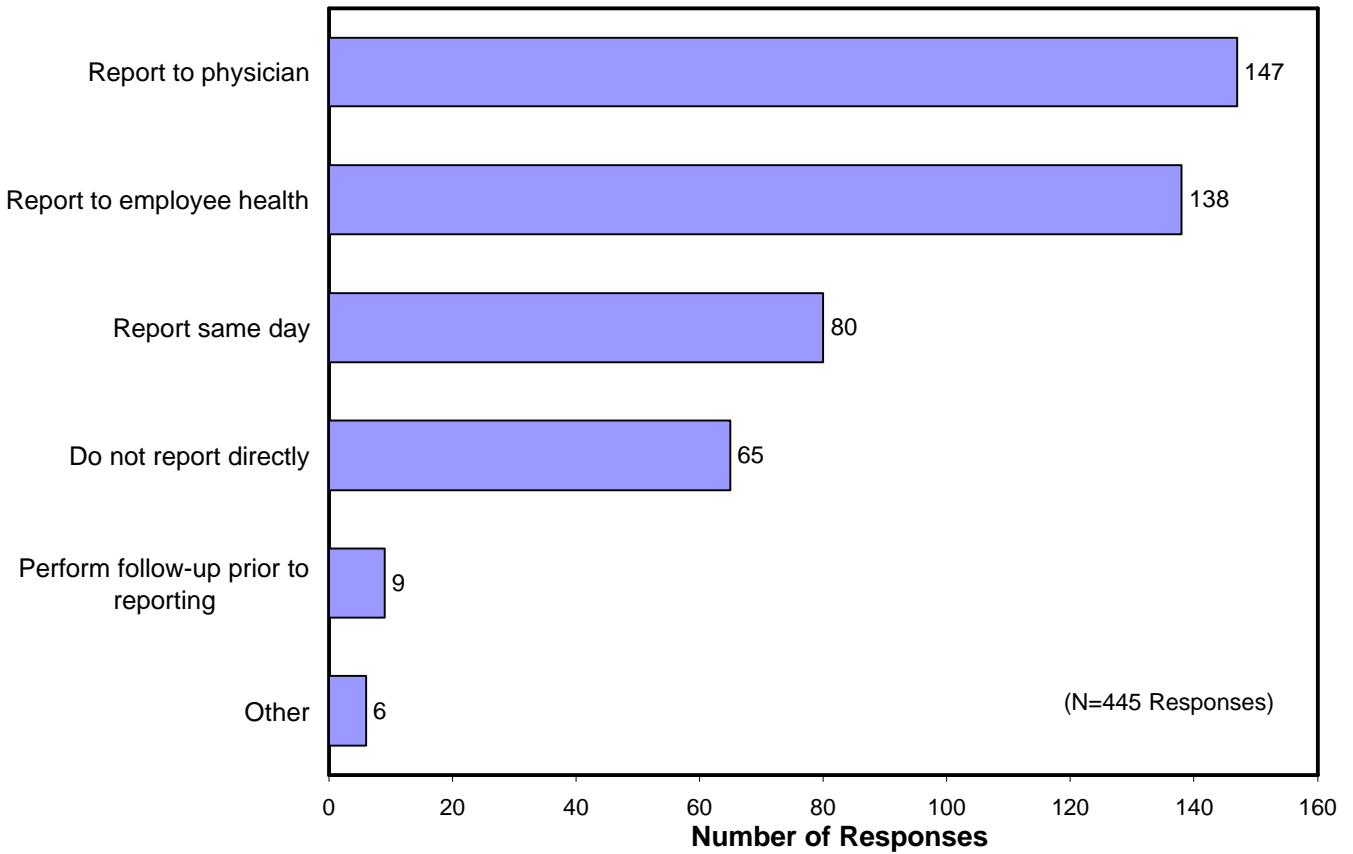
14.(a) What is the typical reporting procedure to the client/patient for an initially reactive (preliminary positive) HIV rapid test? (Check all that apply.)



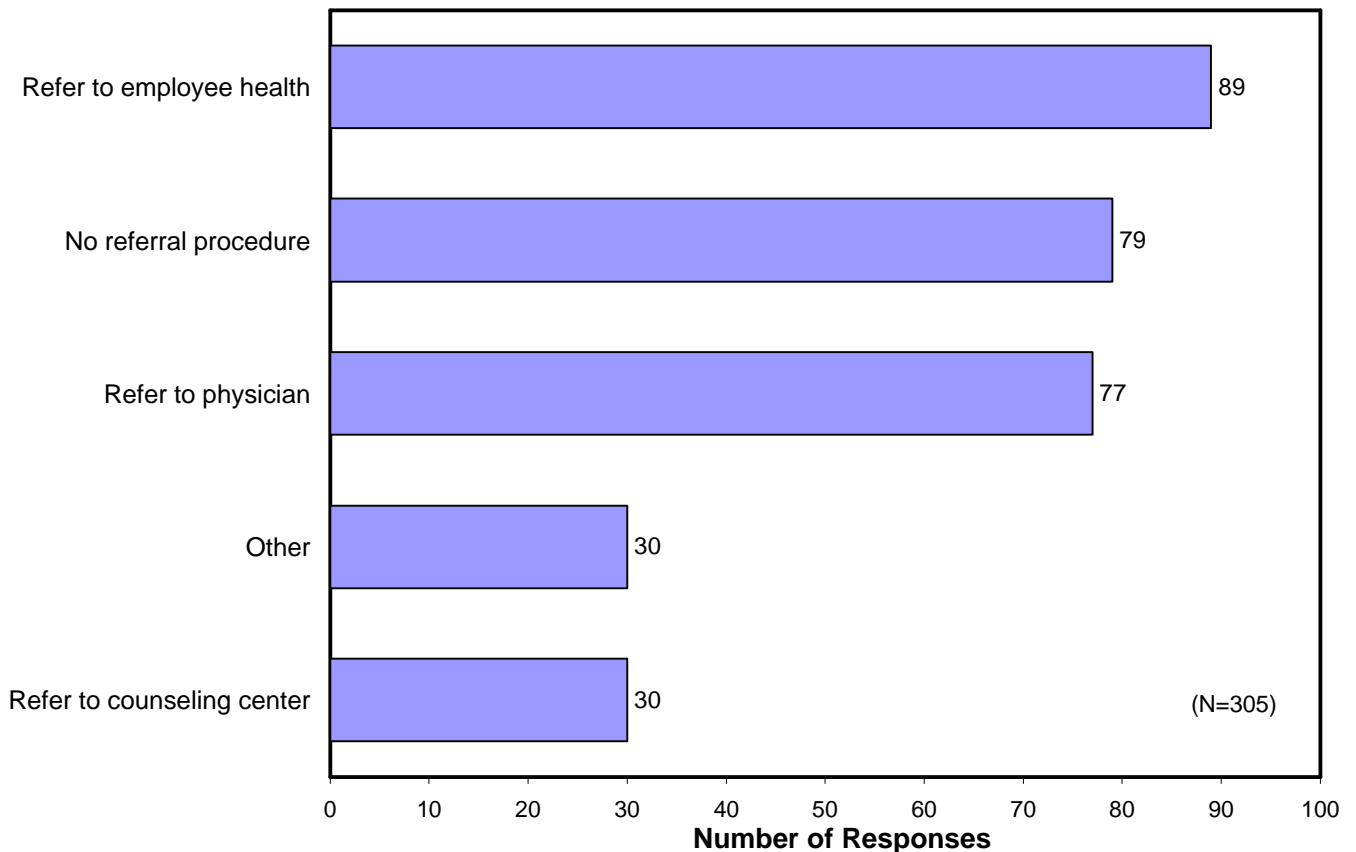
14.(b) What is the typical referral procedure to the client/patient for an initially reactive (preliminary positive) HIV rapid test? (Check all that apply.)



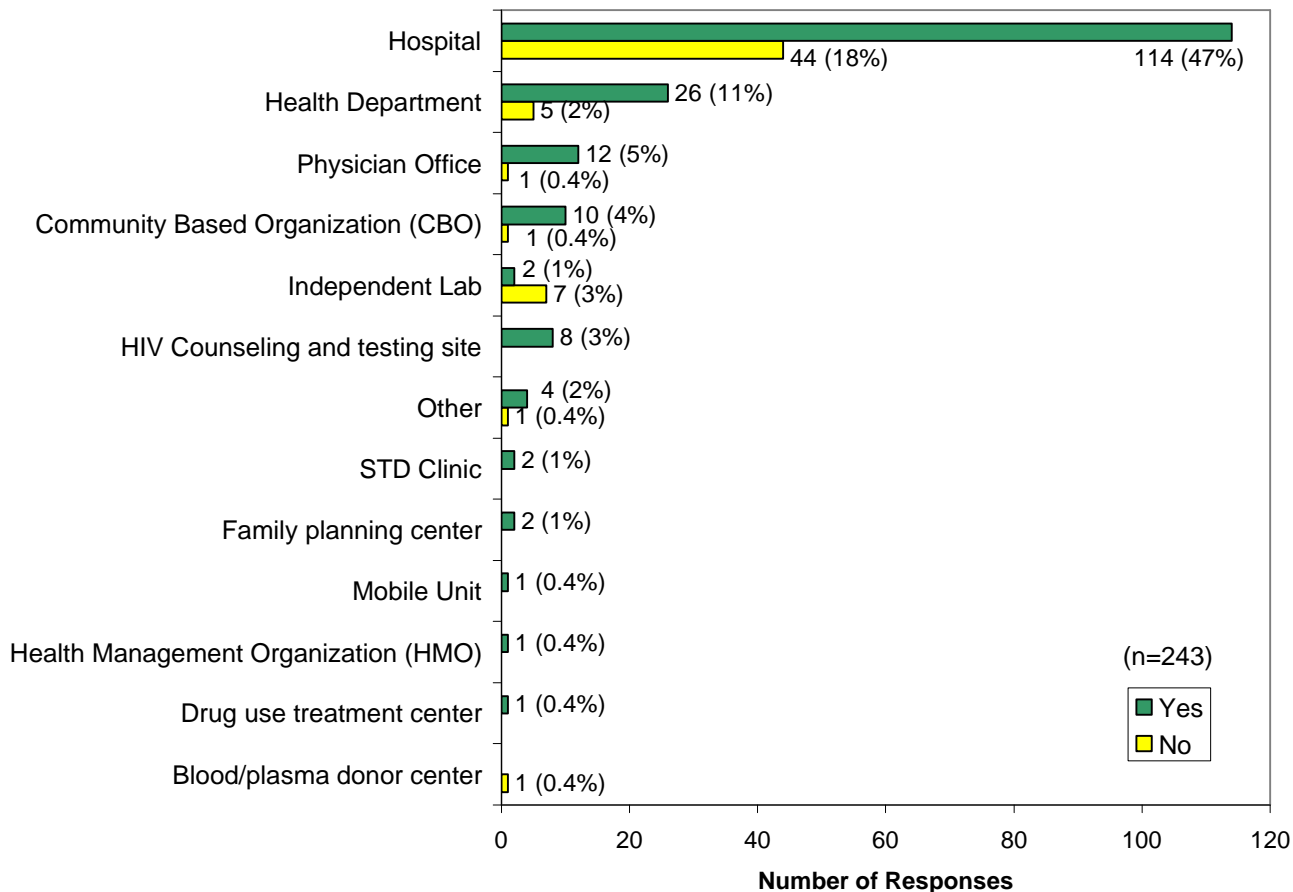
**14.(c) What is the typical reporting procedure to the client/patient for a negative HIV rapid test?
(Check all that apply.)**



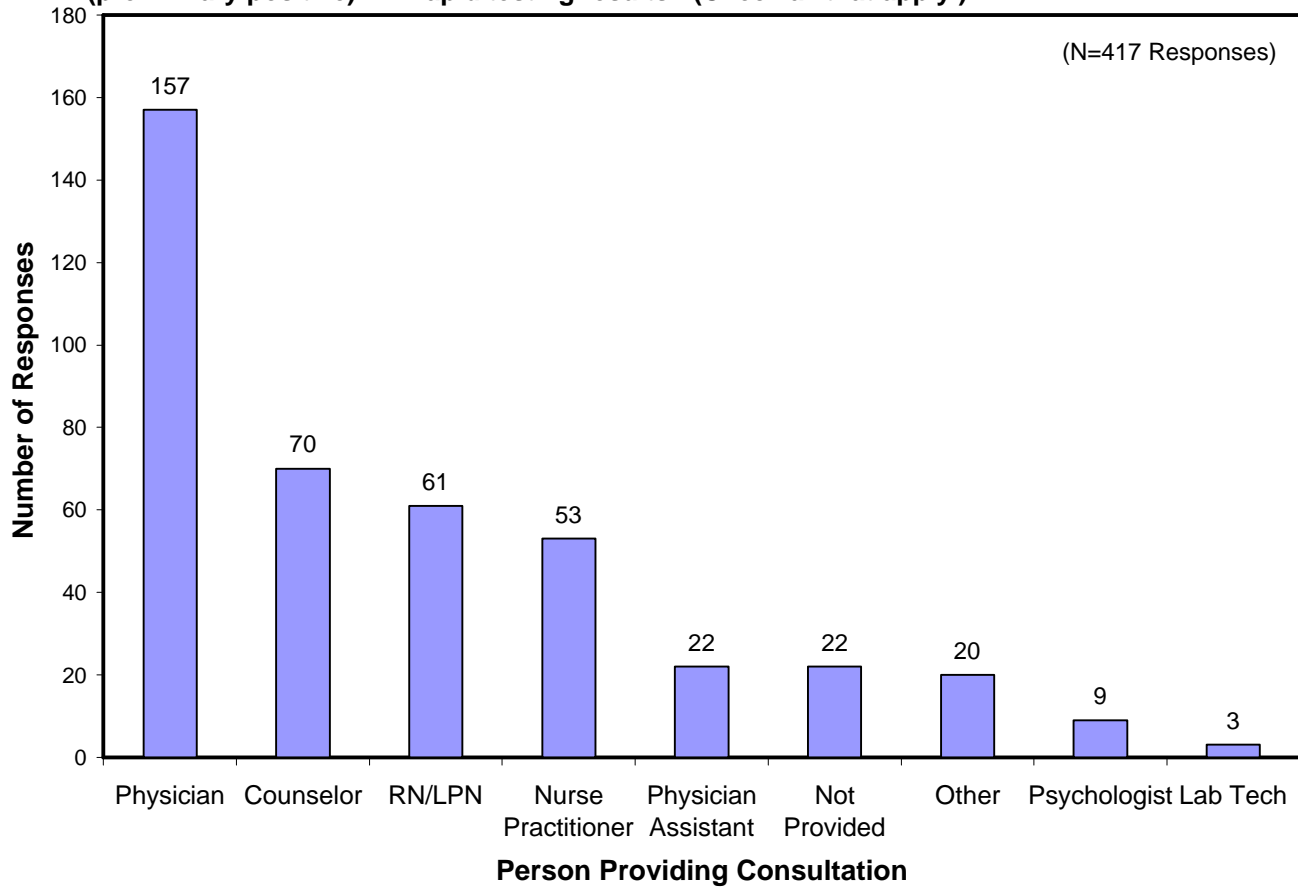
**14.(d) What is the typical referral procedure for the client/patient for a negative HIV rapid test?
(Check all that apply.)**



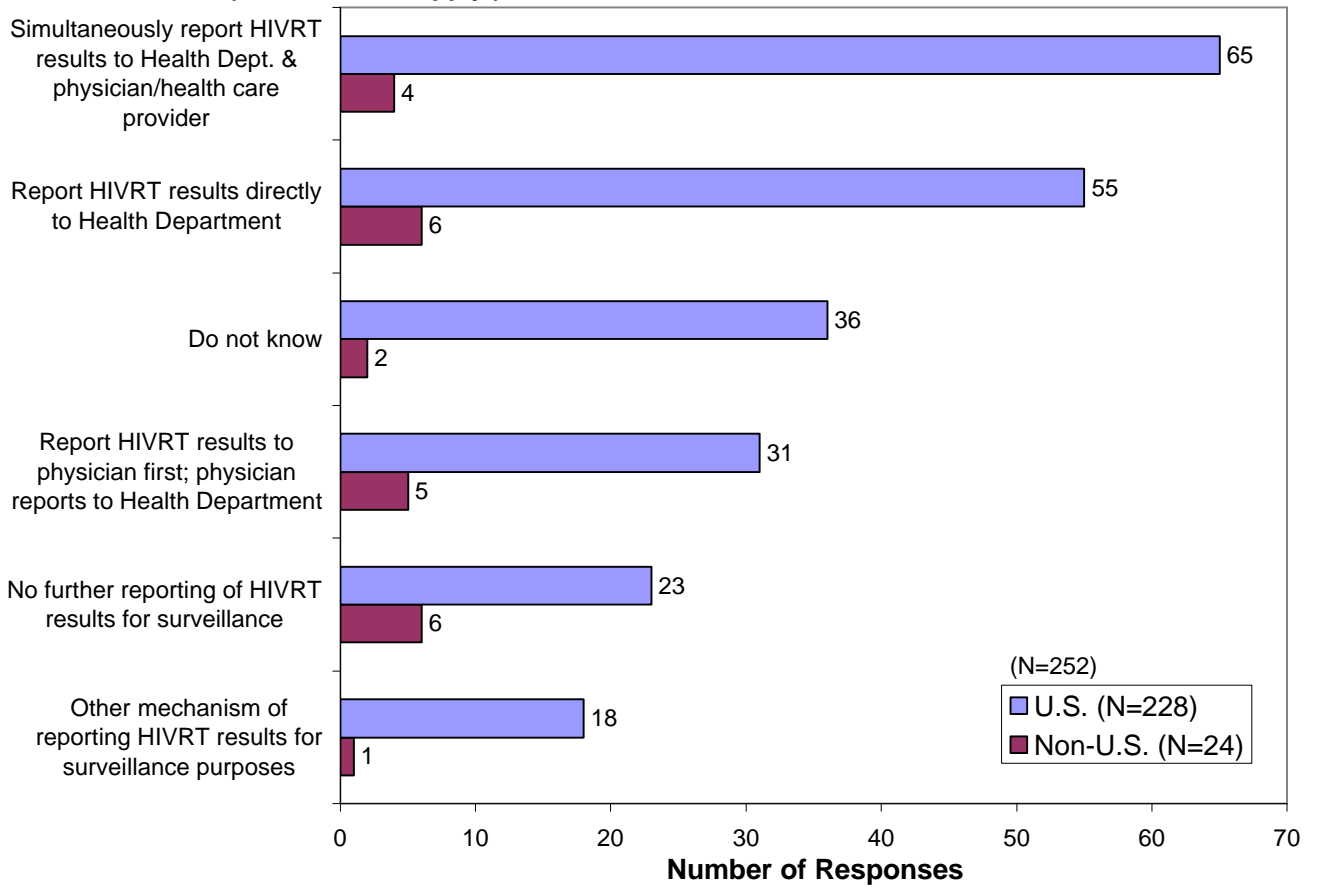
14.(e) Does your facility/testing site provide onsite HIV counseling to clients/patients?



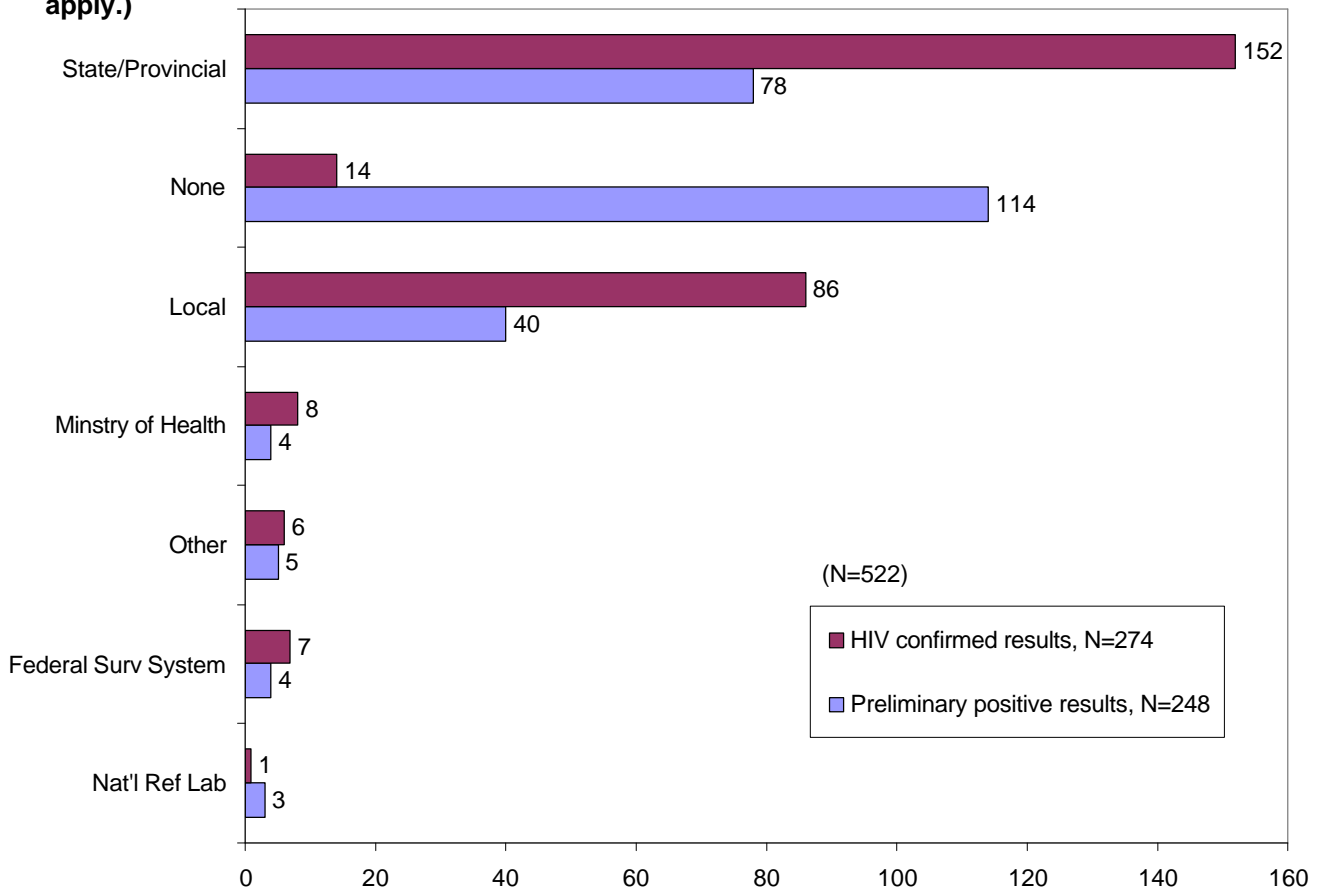
14. (f) At your facility/testing site, who provides client/patient consultation for initially reactive (preliminary positive) HIV rapid testing results? (Check all that apply.)



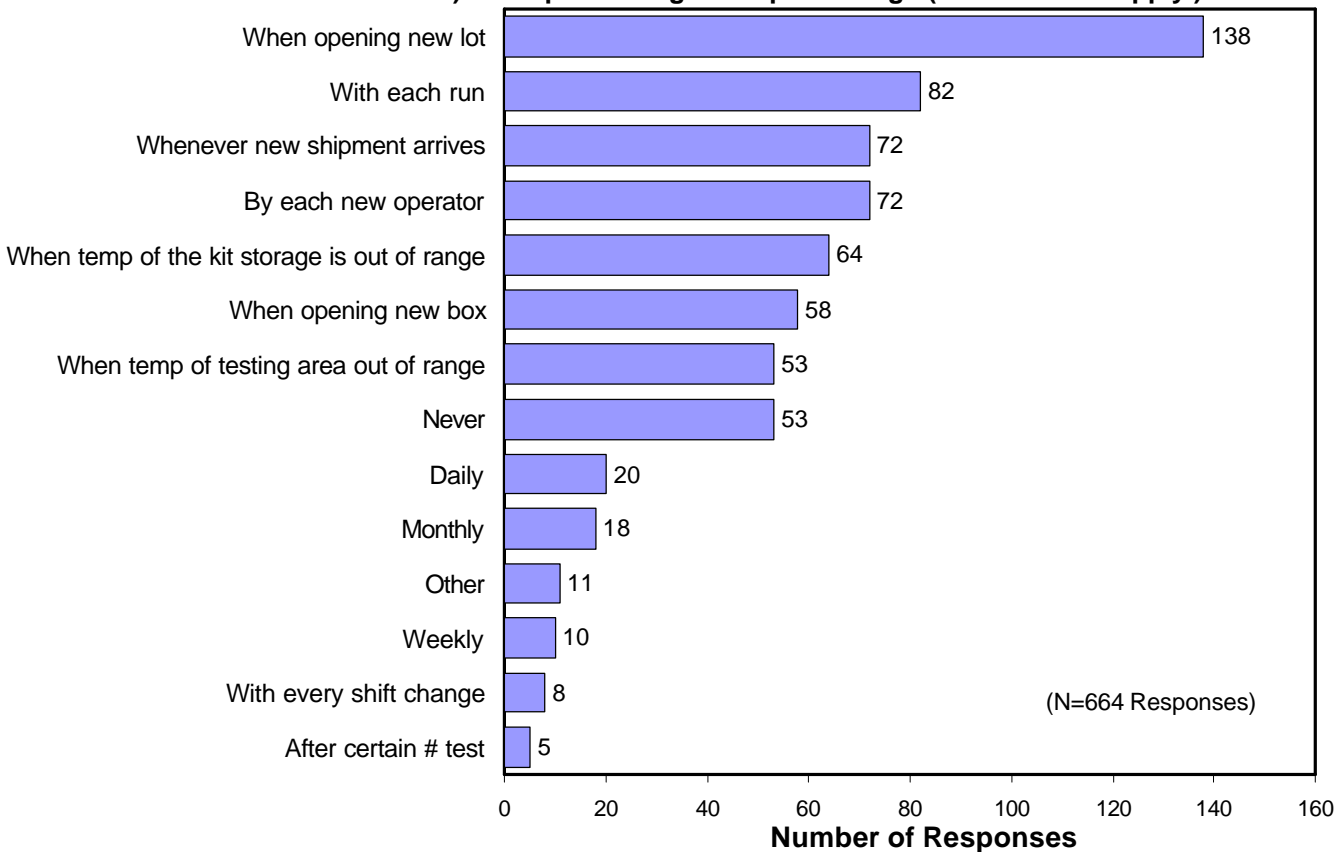
15. (a) What is the typical HIV results reporting procedure(s) for the purposes of HIV surveillance? (Check all that apply.)



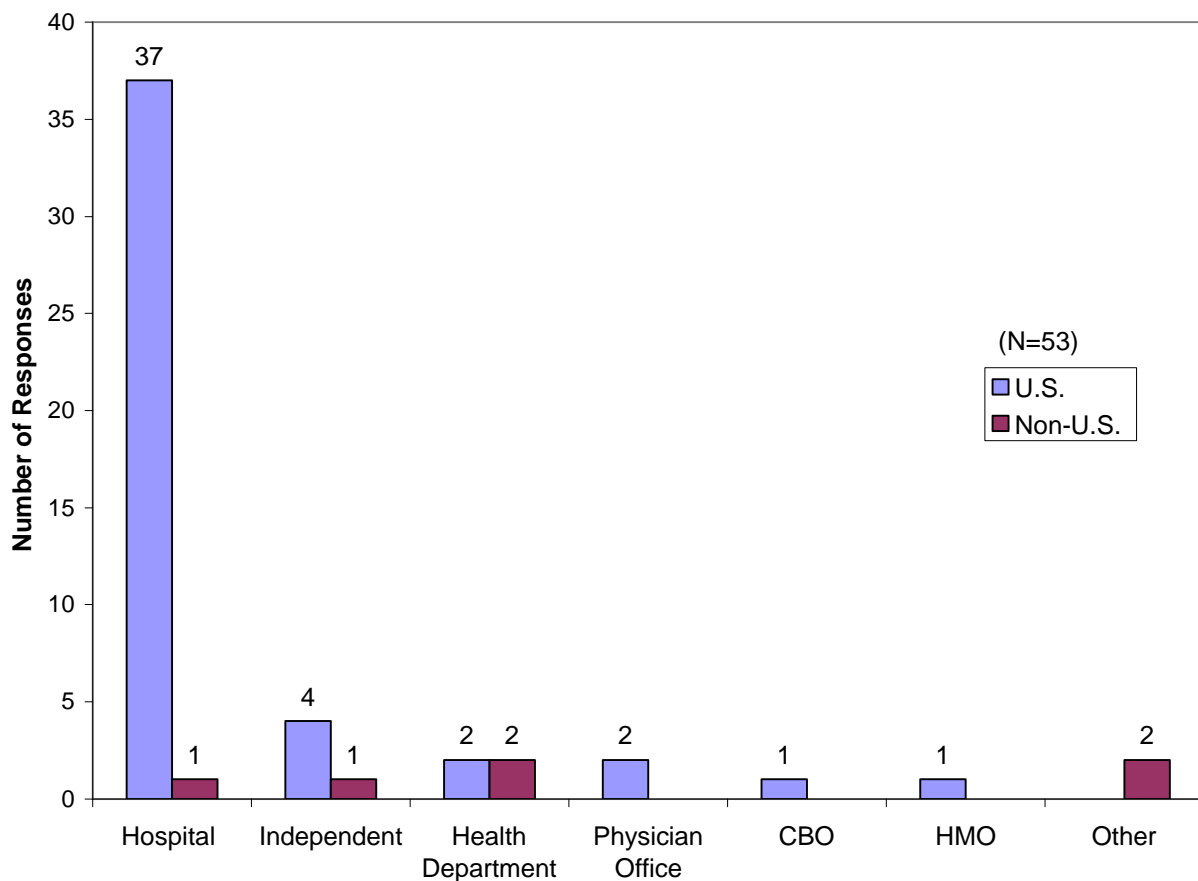
15. (b) To which health departments do you report HIV rapid testing results? (Check all that apply.)



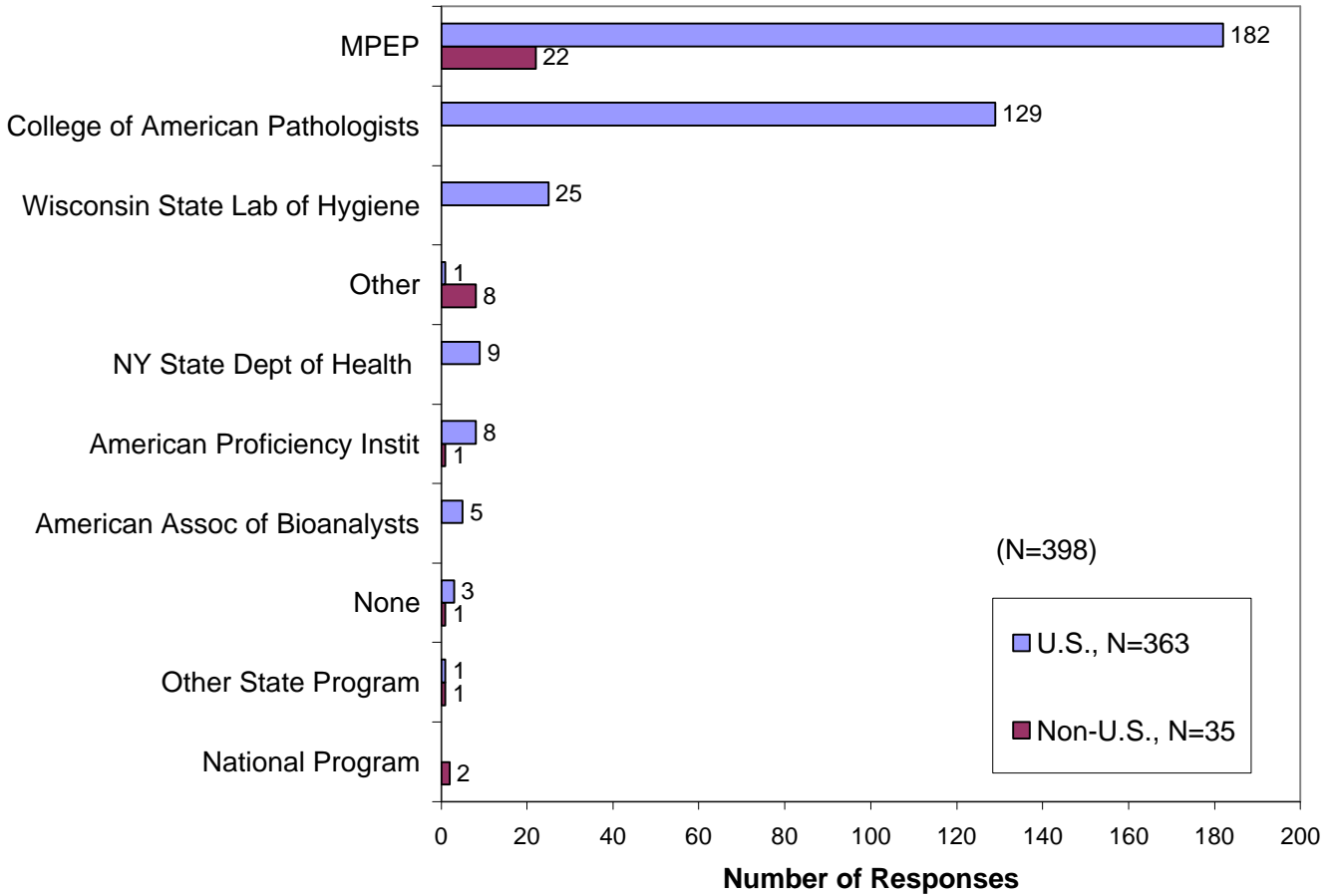
16. How often does your facility/testing site run external controls (positive or negative controls not included in the test kit) when performing HIV rapid testing? (Check all that apply.)



16. (Continued) Facilities Responding 'Never' to Question 16 by Lab Type



17. In which external HIV proficiency testing (PT) or performance evaluation (PE) program(s) does your facility participate? (Check all that apply.)



18. Approximately how much does your facility charge to perform an HIV rapid test? (Round off to nearest U.S. Dollar.)

