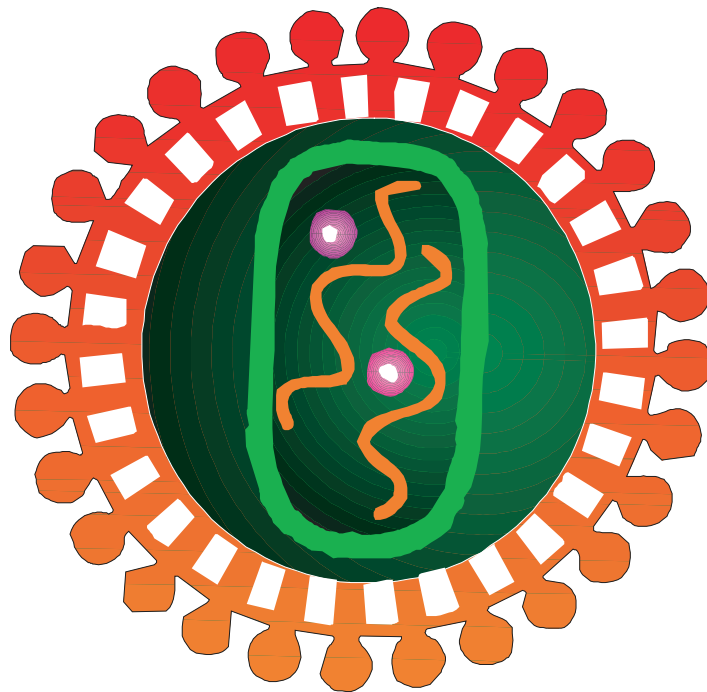




*Questionnaire Results:*  
*HIV Rapid Testing*  
*Survey 2005*



DEPARTMENT OF HEALTH & HUMAN SERVICES



# HIV-1 Rapid Testing MPEP 2005 Survey Questionnaire Report of Results

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Report of the August 2005 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).

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# Executive Summary of Results

## HIV Rapid Testing Questionnaire Survey, August 2005

### Survey Description

The accompanying report details the results from the third CDC Model Performance Evaluation Program (MPEP) HIV Rapid Testing Practices Survey conducted during 2005. 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 354 (68.1%) of the 520 HIV-RT testing sites enrolled. The distribution of respondents compared with non-respondents was constant across testing site types. The survey participants included 318 U.S. testing sites and 36 non-U.S. testing sites.

### Results Summary

#### Survey Participants and Test Use

Most survey respondents were from hospital laboratories (54%). However, 27% (96/354) of the respondents were from non-traditional or outreach testing sites, i.e. sites other than hospitals, HMOs, health departments, independent laboratories, or blood banks (Figure 1a). Survey participants said they performed HIV rapid tests on specimens that were collected in a variety of off-site locations, such as community-based organizations, counseling and testing centers, correctional facilities and drug treatment centers (Figure 7b). Within hospitals, the reporting of a variety of secondary testing sites indicated (Figures 1a and Figures 7a and 7b) that HIV rapid testing was being used for different purposes including post-exposure treatment, voluntary testing, screening, testing pregnant women, and emergency room screening (Figure 3a). Over one-half of the participants used HIV rapid tests for voluntary testing and/or initial screening. The percentages were higher in non-traditional/outreach sites (76% - 100%).

#### Test Volume and Results

The median number of HIV rapid tests performed in the most recent representative month calculated from the responses was 20, although the range was from 0 - 10000 tests, with the highest volume sites being outside the U.S. (Figure 3d). All sites reporting that they perform 1000 or more tests/month were non-U.S. facilities.

A relatively high percentage of outreach sites performed 100 tests or more during the most recent month (39% - 55%). Most of the U.S. testing sites (69%) reported that none of the HIV rapid tests performed on client/patient specimens in the most recent representative month were positive; 68% of these performed less than 20 tests per month. A high percentage of outreach sites reported that 1% or more of the client/patient specimens tested yielded preliminary positive results, i.e. 50% - 86%, based on site type (Figure 3e). Although numbers are small, nearly half (46%) of the non-U.S. testing sites reported that >10% HIV rapid tests were positive in the most recent representative month (Figure 3e). Most testing sites (87%) reported that 90 -100% of the initially reactive (preliminary positive) results were confirmed as positive.

#### Test Kits

The predominant kit types used by U.S. testing facilities were OraQuick ADVANCE Rapid HIV-1/2 Ab tests (52%), MedMira Reveal G2 Rapid HIV-1 Ab tests (23%), and OraSure OraQuick Rapid HIV-1 (20%). (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 types used by non-U.S. testing sites were Abbott Determine HIV-1/2 (64%) and Trinity Biotech Capillus HIV (22%) although a variety of kit types were reported by these testing facilities (Figure 5). Participants frequently performed other HIV tests in their facilities (Figure 8). Twenty percent of respondents reported that HIV rapid tests replaced other HIV testing methods in their facility.

### Testing Personnel

HIV rapid tests were primarily performed by medical technologists, medical technicians, persons with a BS/BA in laboratory sciences, HIV counselors and persons with an associate's degree (Figure 10). This pattern reflects the types of personnel employed in the facilities participating, with the majority being hospitals. Almost half of the respondents (49%) reported that training on rapid HIV testing was conducted in-house. The median length of training was for two hours (Figure 11). Most facilities (74%) provided onsite counseling to clients/patients (Figure 14e), and most counseling was provided by physicians, counselors, RN/LPNs or nurse practitioners (83% 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 18/277 (6%) U.S. testing sites describing methods used for confirmatory testing did not use either Western blot (WB) or an indirect immunofluorescence assay (IFA), the confirmatory methods recommended by current CDC guidelines (Figure 12b). (1, 2)

### Quality Control

Most facilities (88%) said they ran external quality control samples when performing HIV rapid testing (Figure 16). Participants could give more than one response to this question. However, it is of concern that 12% of participants reported never running external quality control samples. Most of these were U.S. testing sites. Testing external 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. CDC HIV-RT MPEP will continue to monitor laboratory practices in HIV rapid testing.

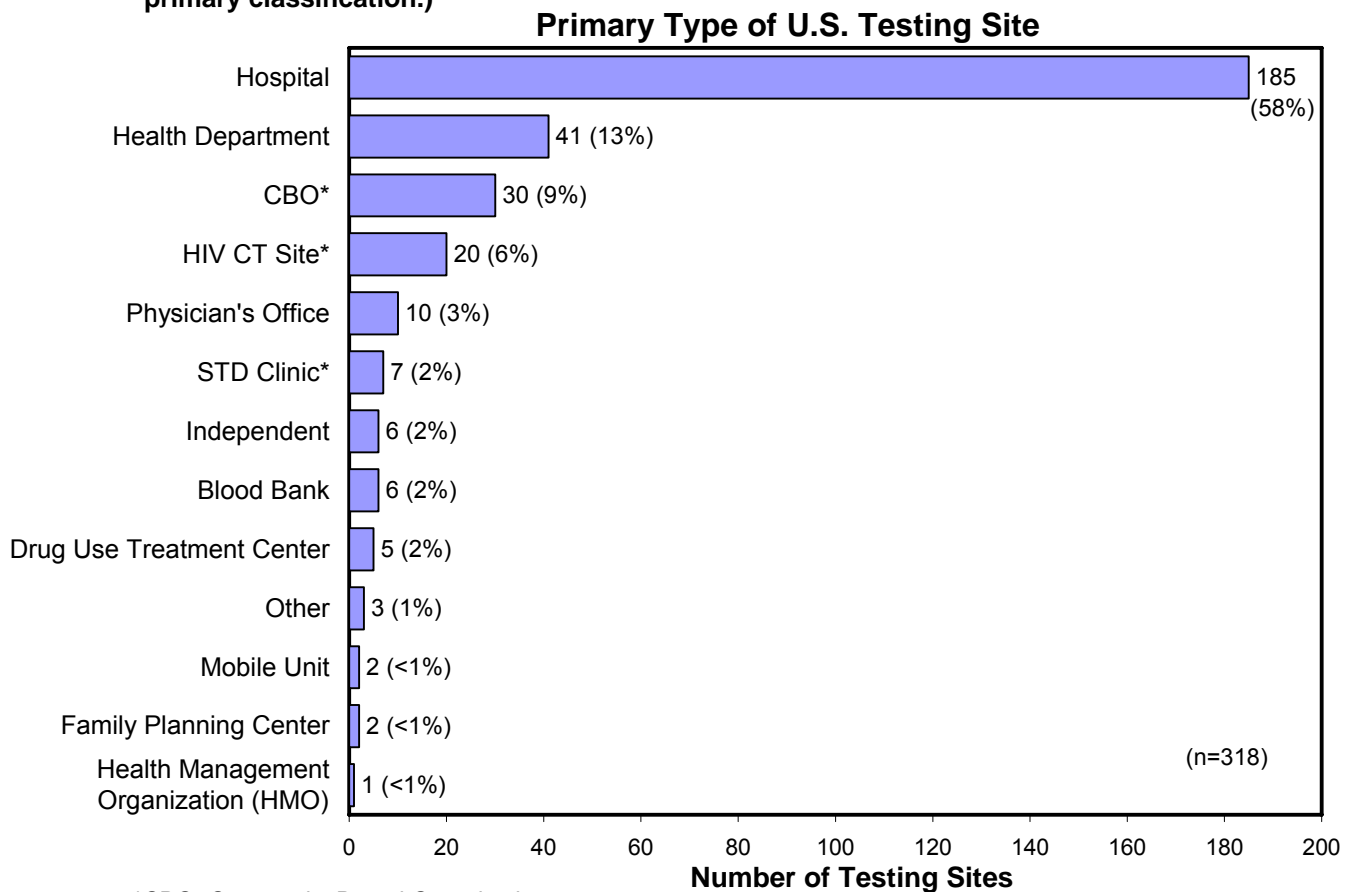
The results presented here reflect a wide range of laboratory/testing site practices in HIV rapid testing among MPEP participants. With changing and evolving testing practices, HIV testing sites should be especially concerned about quality assurance, and should be aware of existing guidelines and recommendations. 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> Recommendations for good laboratory practices for sites performing waived tests have recently been published by CDC and can be accessed at : <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5413a1.htm> (3).

## **References:**

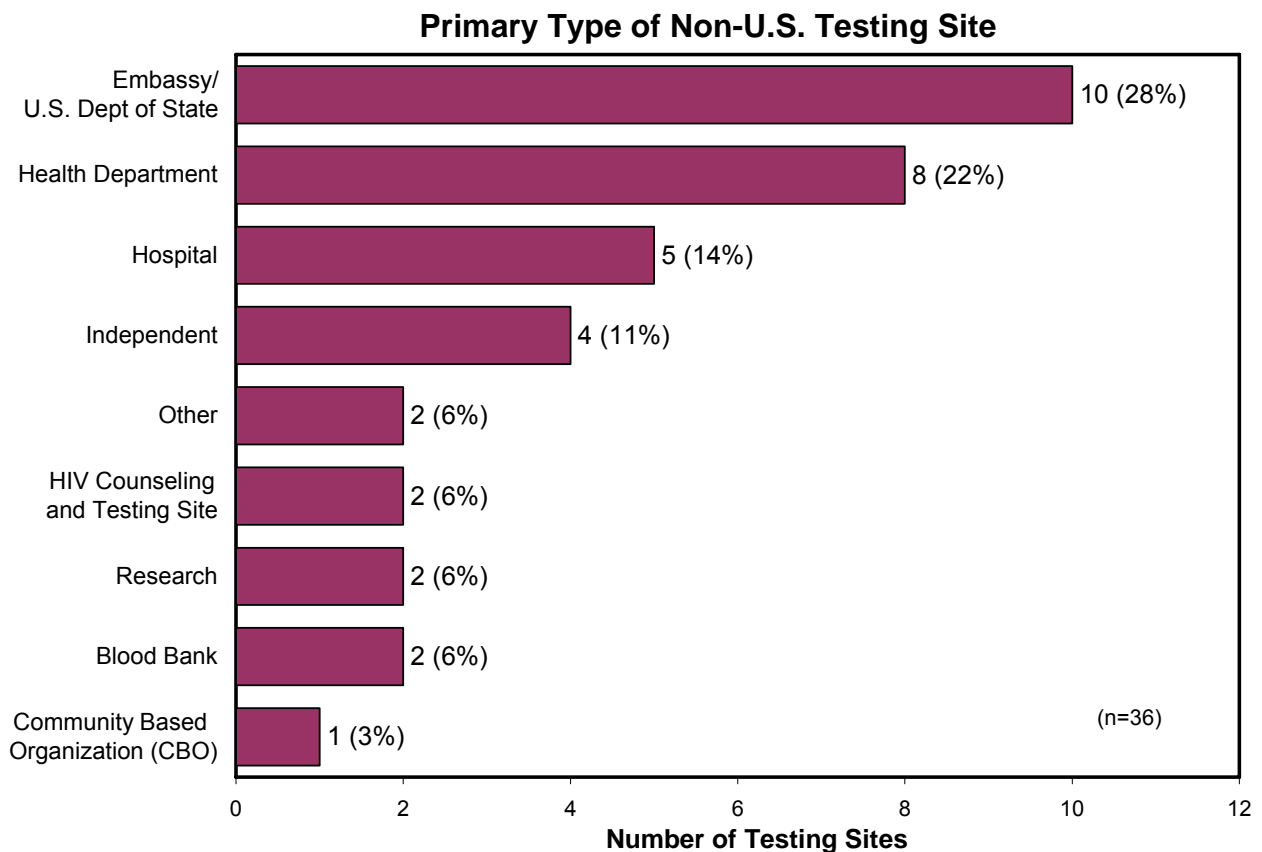
- 1) Quality Assurance Guidelines for Testing Using the OraQuick Rapid HIV-1 Antibody Test. Centers for Disease Control and Prevention, U.S. Department of Health and Human Services. 2003. [http://www.cdc.gov/hiv/rapid\\_testing/materials/QA-Guide.htm](http://www.cdc.gov/hiv/rapid_testing/materials/QA-Guide.htm).
- 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>.
- 3) CDC. Good Laboratory Practices for Waived Testing Sites, MMWR Recommendations and Reports. 2005: 54(RR13); 1-25.

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

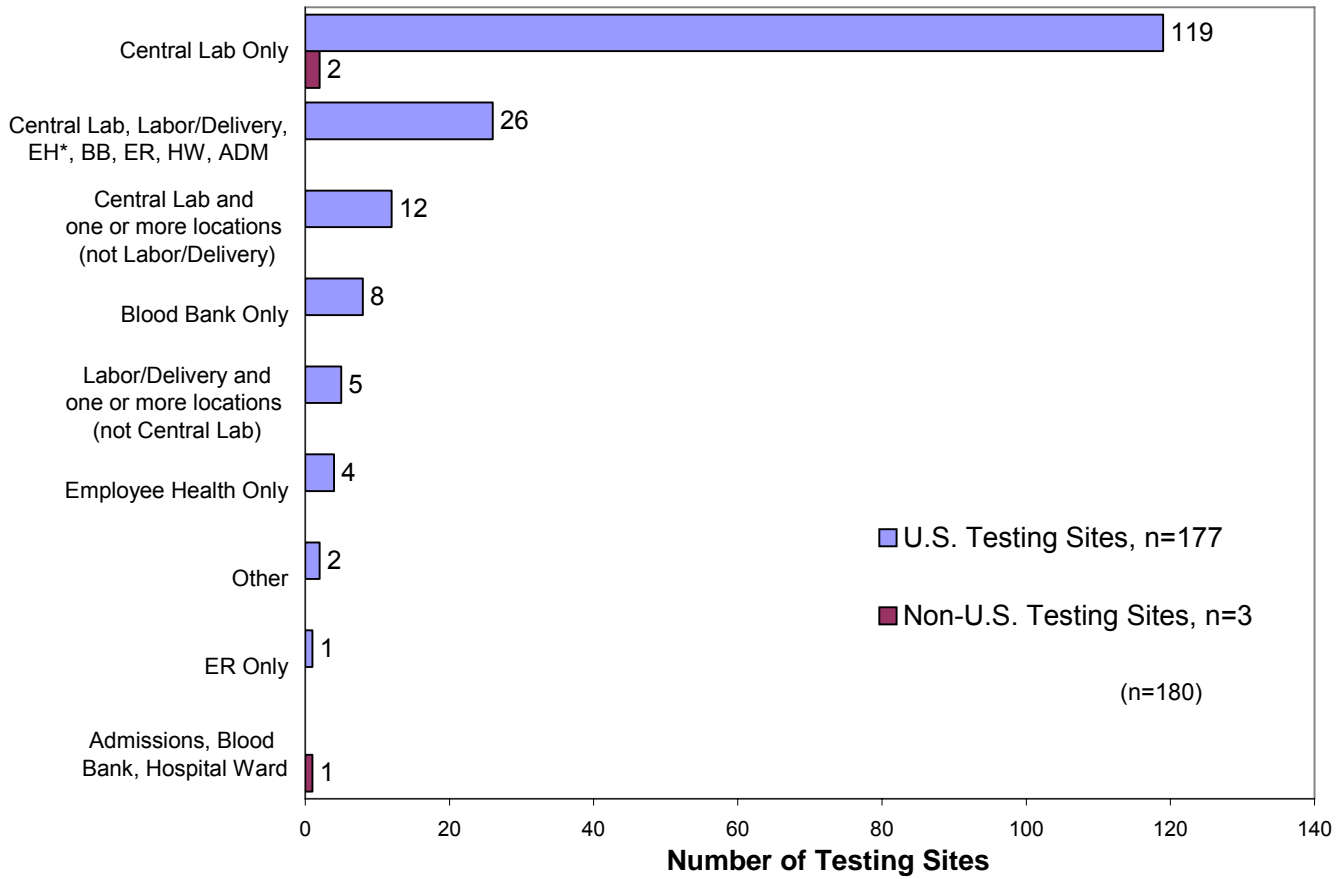
1.(a) Please indicate the primary classification of your facility/testing site. (Check one primary classification.)



\*CBO=Community Based Organization  
 HIV CT Site=HIV Counseling and Testing Site  
 STD Clinic=Sexually transmitted disease Clinic



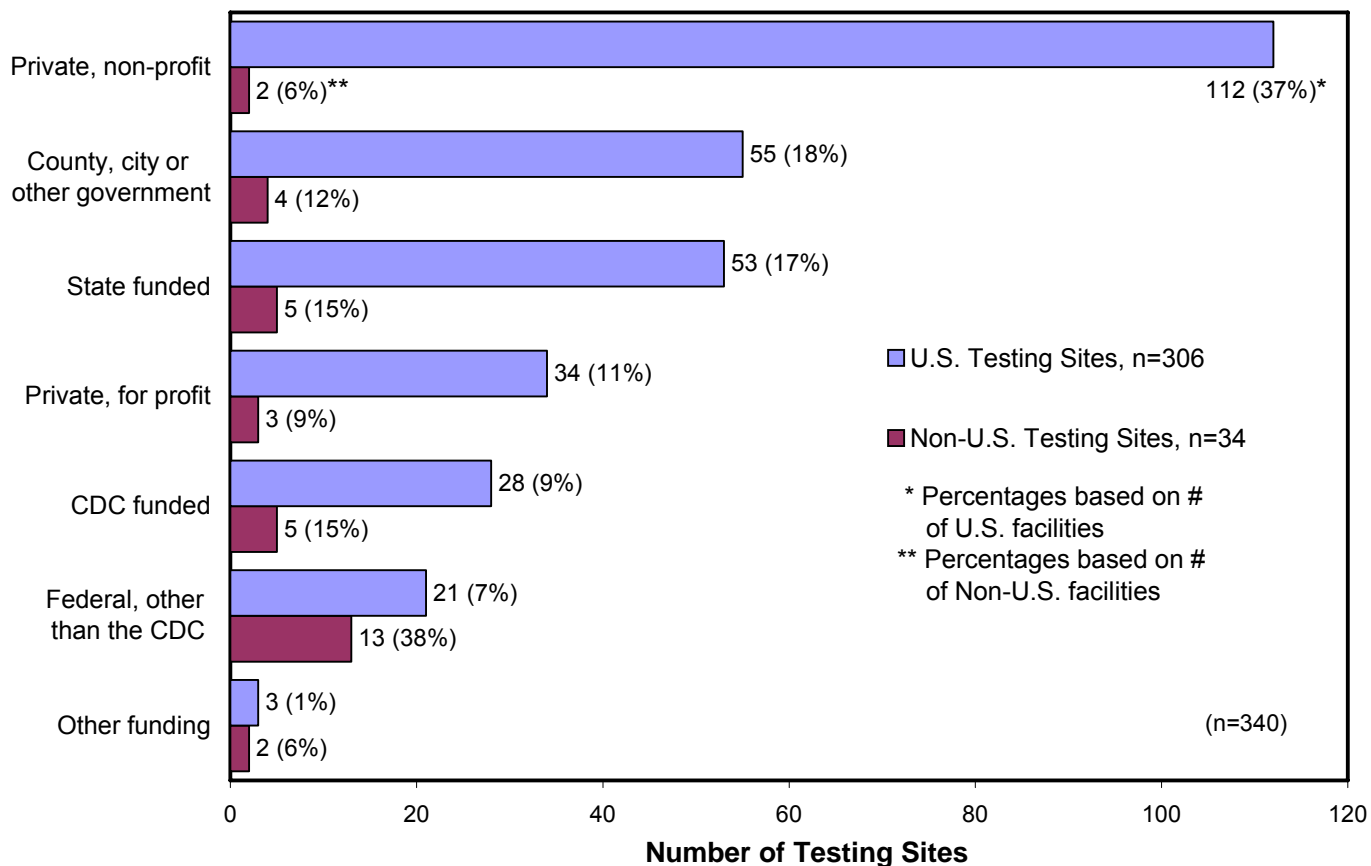
## Testing Sites within Hospitals



Please note: the total number of sites represented in this figure (n=180) reflects the number of hospital sites that answered the question.

- \* EH = Employee Health
- BB = Blood Bank
- ER = Emergency Room
- HW = Hospital Ward
- ADM = Admissions

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



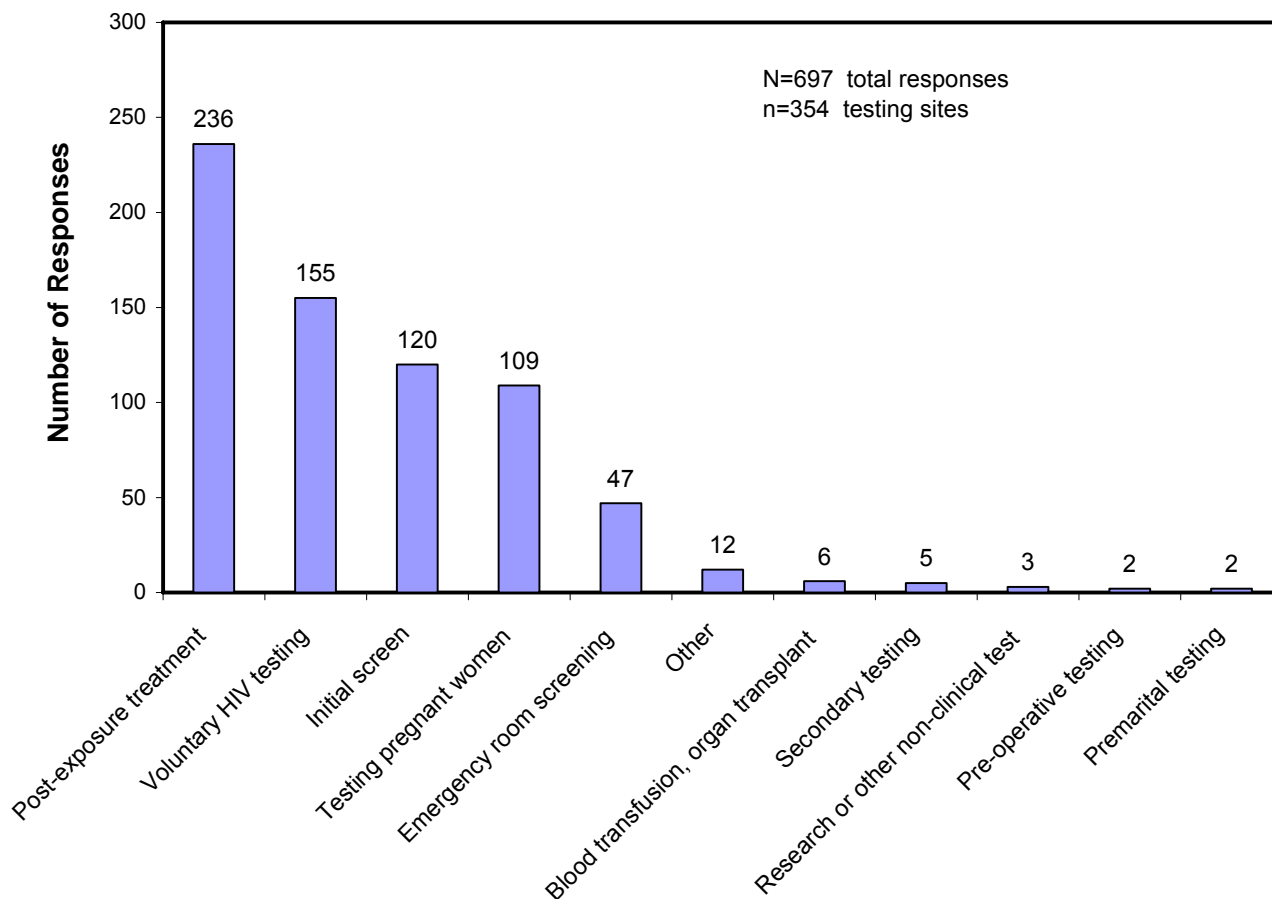
**2.(a) Does your facility currently perform HIV rapid testing?**

Response	Number of Facilities (%) (n=354)
Yes	348 (98%)
No	6 (2%)

**2.(b) In the future, will your facility begin performing HIV rapid testing? (Choose only one)**

Response	Number of Facilities (%) (n=6)
Within 6 months	2 (33%)
No	2 (33%)
Within 12 months	1 (17%)
Yes, unsure when	1 (17%)

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



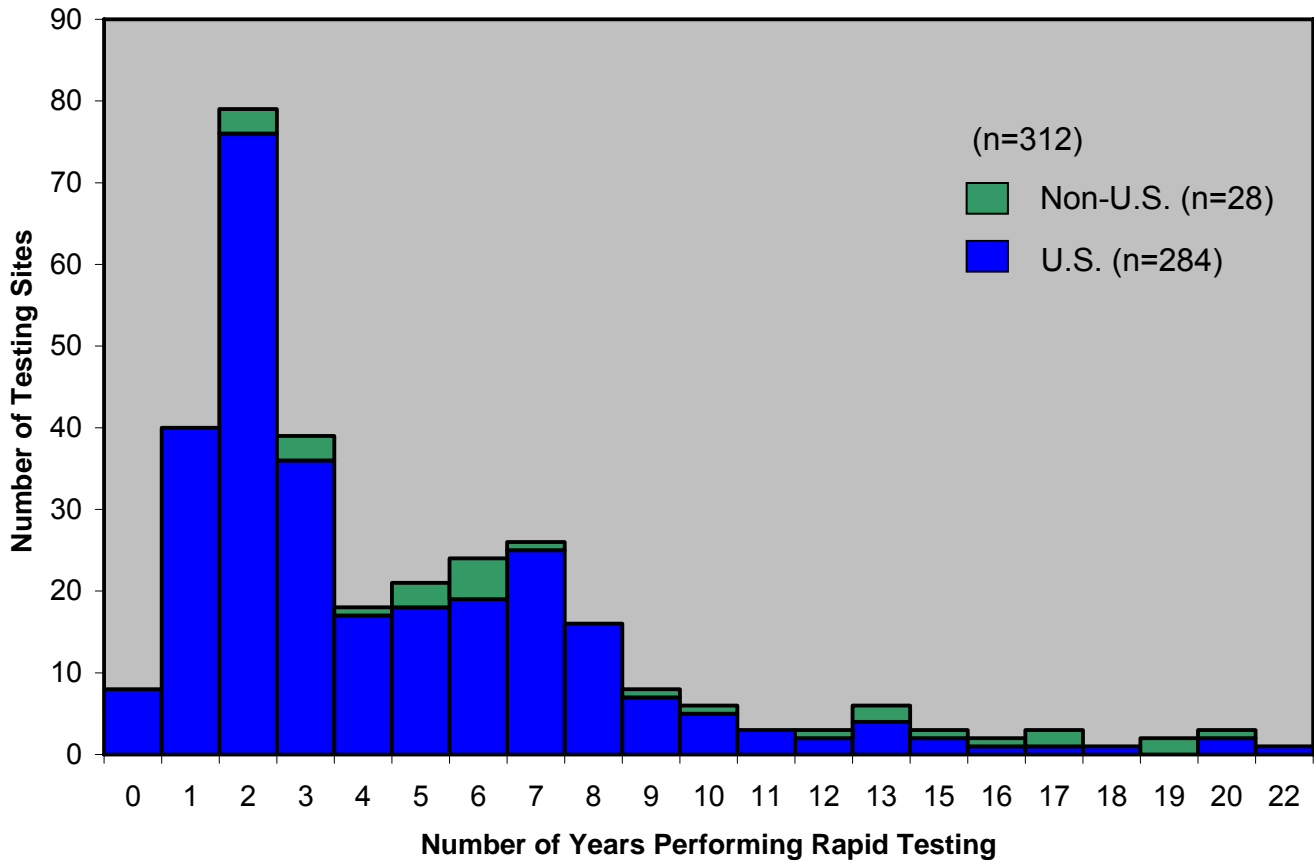
Note: Facilities could submit more than one answer.

Half (51%, 182/354) of the participants who 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 of these purposes for testing are listed below.

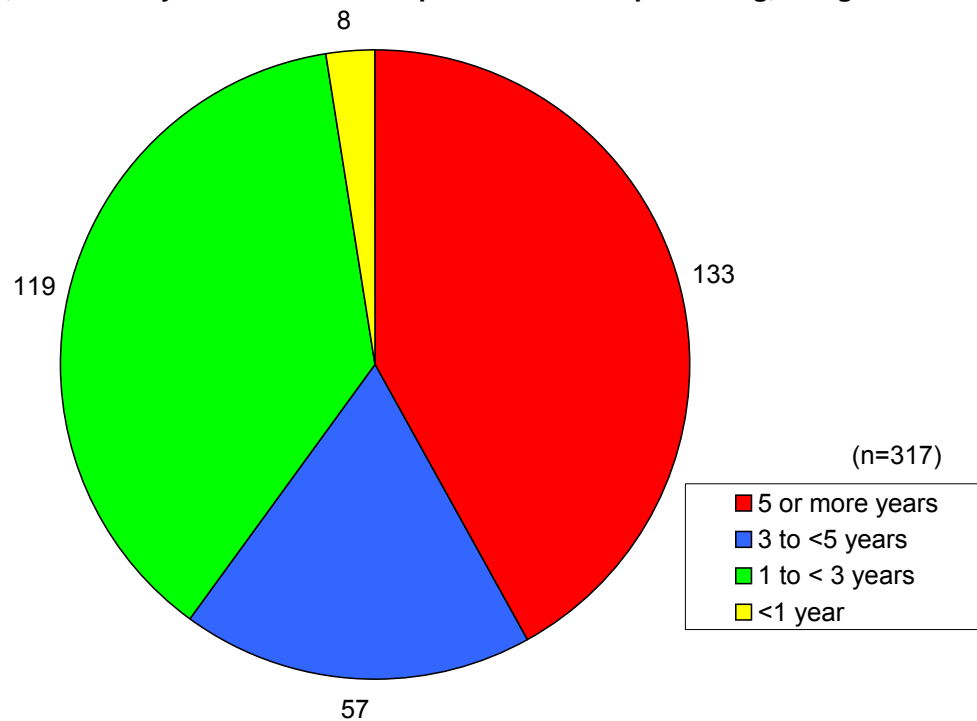
- hospitals: 27% (52/190),
- health departments: 73% (36/49),
- physicians office: 90% (9/10),
- community-based organization (CBO): 94% (29/31),
- counseling and testing sites: 100% (22/22)
- other testing sites: 76% (13/17)
- independent sites: 50% (5/10)
- family planning centers: 100% (2/2),
- STD clinics: 100% (7/7), and
- blood/plasma donor center, drug treatment center, health management organization (HMO), and mobile unit: 44% (7/16).



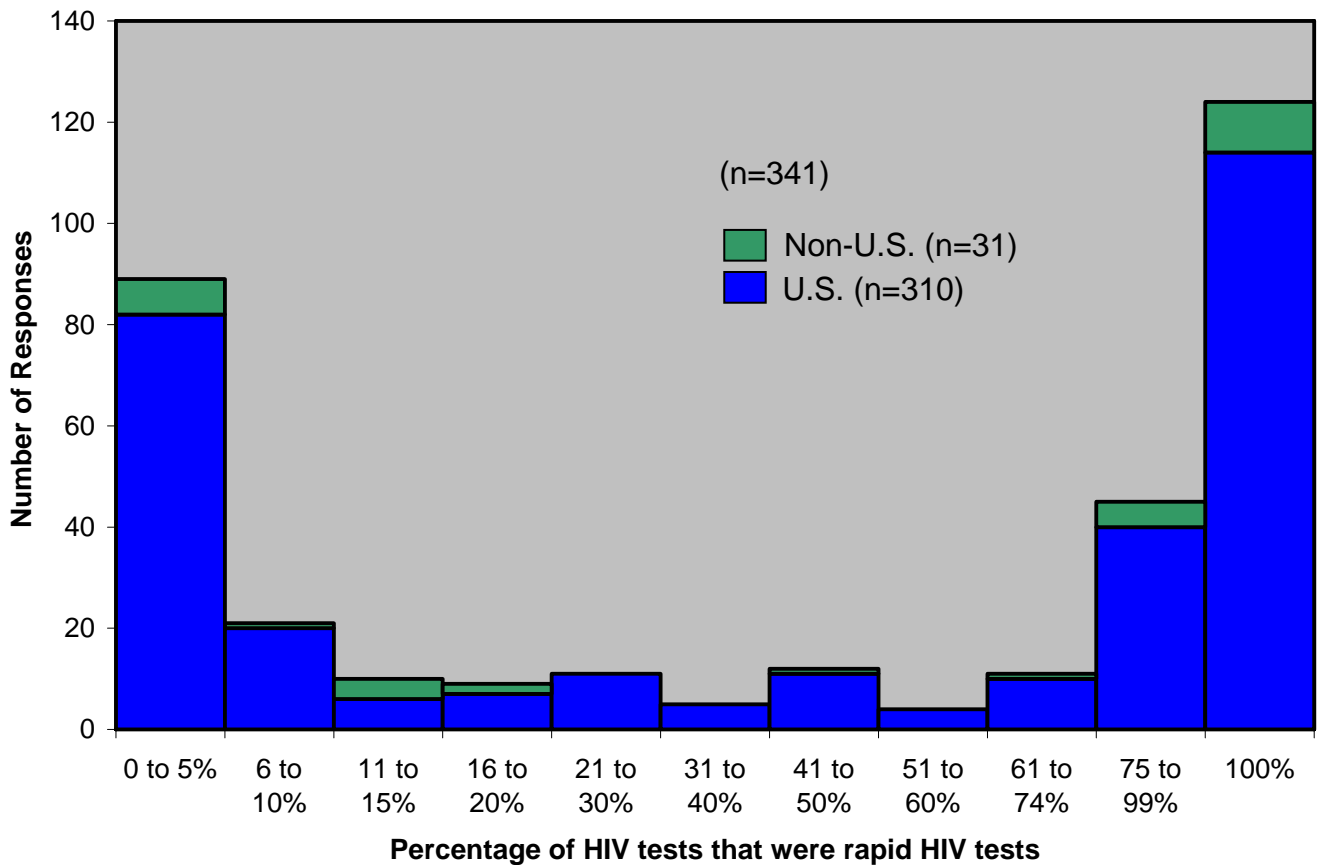
3.(b) When did your facility begin to perform HIV rapid testing?



3.(b) Continued, Number of years facilities have performed HIV rapid testing, categorized



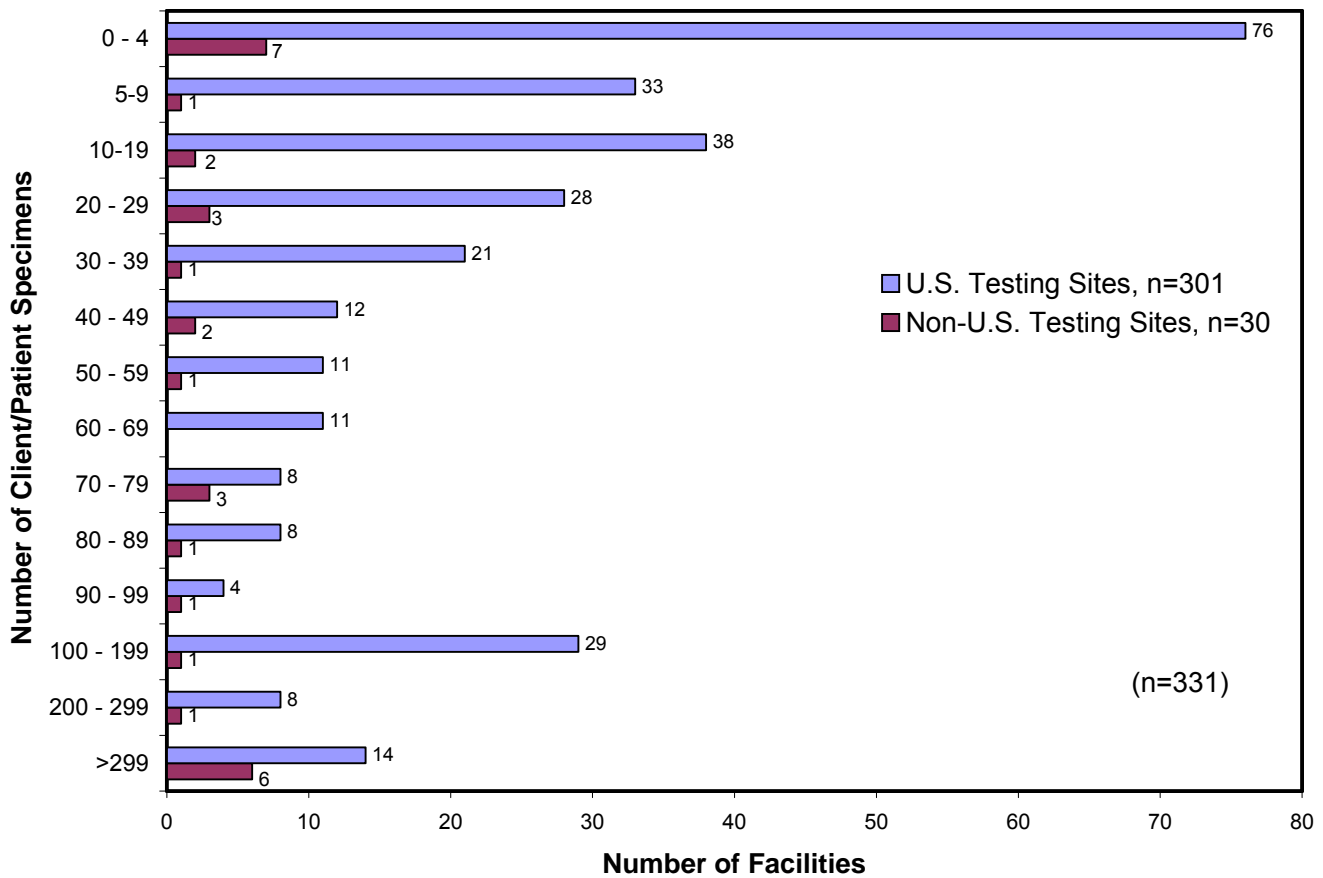
3.(c) Of all HIV testing performed in your facility over the past year, what percentage was performed using HIV rapid test kits? (Please round off to the nearest whole percentage.)



The graph of the data for this question is bimodal, with most responses being either less than or equal to 10% or >75%. 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 %	75-99%	100%
Hospital	40% (76/190)	3% (6/190)	44% (84/190)
Health Department	31% (15/49)	14% (7/49)	14% (7/49)
Independent			20% (2/10)
Physician Office	10% (1/10)	20% (2/10)	50% (5/10)
CBO	3% (1/31)	26% (8/31)	39% (12/31)
Counseling & Testing Site	5% (1/22)	50% (11/22)	18% (4/22)
“Other”	29% (5/17)	29% (5/17)	29% (5/17)
Drug Treatment, Mobile Unit		14% (1/7)	57% (4/7)
STD Clinic	14% (1/7)	43% (3/7)	
Blood Bank	38% (3/8)	25% (2/8)	

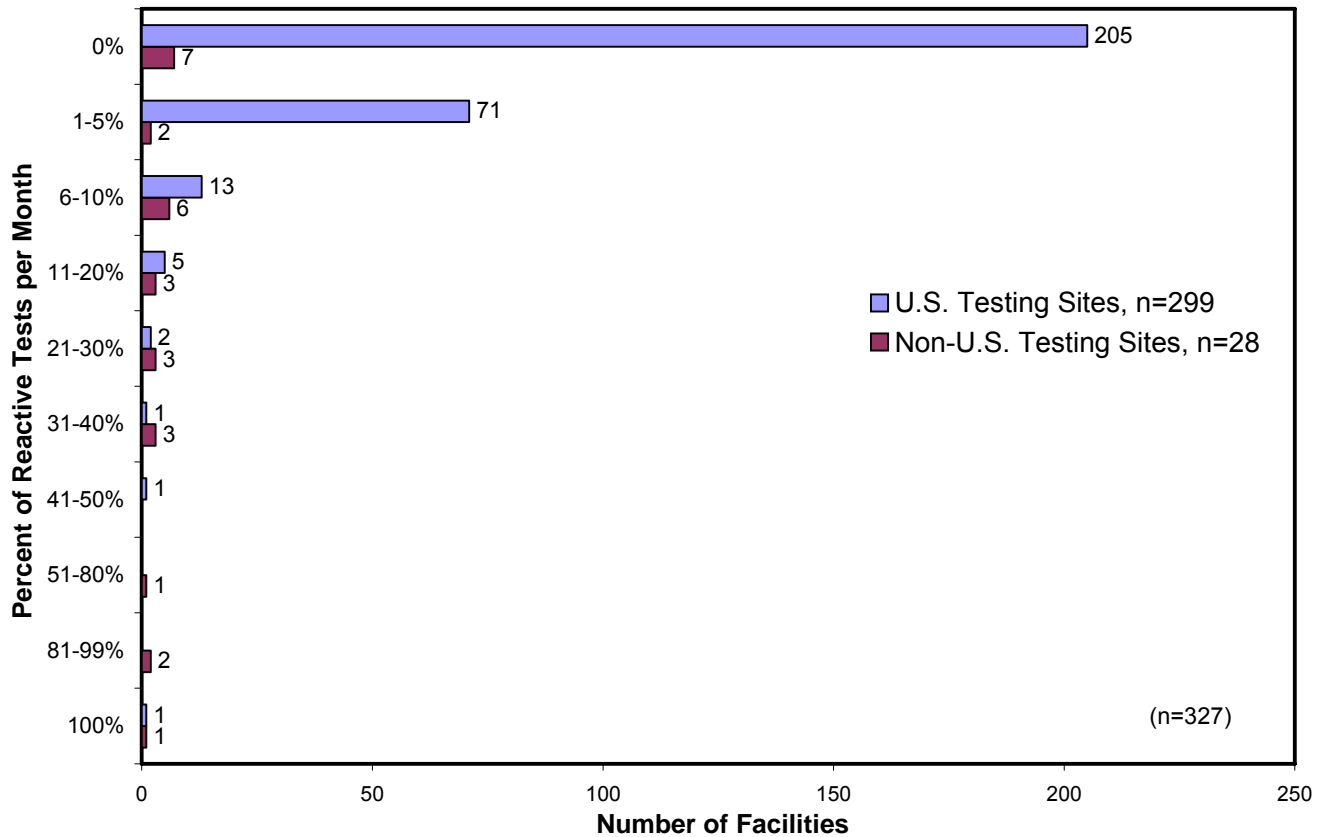
3.(d) How many client/patient specimens were tested using HIV rapid tests in your facility during the most recent representative month? (Please round off to the nearest whole number.)



•The graph of the data for this question appears bimodal; with most responses being either ≤ 30 specimens or ≥ 100 specimens tested using HIV rapid tests (RT).

Facility type	Number of Specimens Tested in the Most Recent Month	
	At least 10 HIV RT/representative month	≥ 100 HIV RT/representative month
Hospital	49% (93/190)	8% (15/190)
Health Department	73% (36/49)	22% (11/49)
Independent	60% (6/10)	10% (1/10)
Physician Office	70% (7/10)	10% (1/10)
Community Based Org (CBO)	90% (28/31)	39% (12/31)
“Other”	41% (7/17)	6% (1/17)
Drug Treatment Center, Mobile Unit, STD Clinic	71% (10/14)	43% (6/14)
Family Planning Center	50% (1/2)	
Blood/Plasma Donor Center	63% (5/8)	
Counseling and Testing Center	95% (21/22)	55% (12/22)
Health Management Org (HMO)	100% (1/1)	

3.(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.)



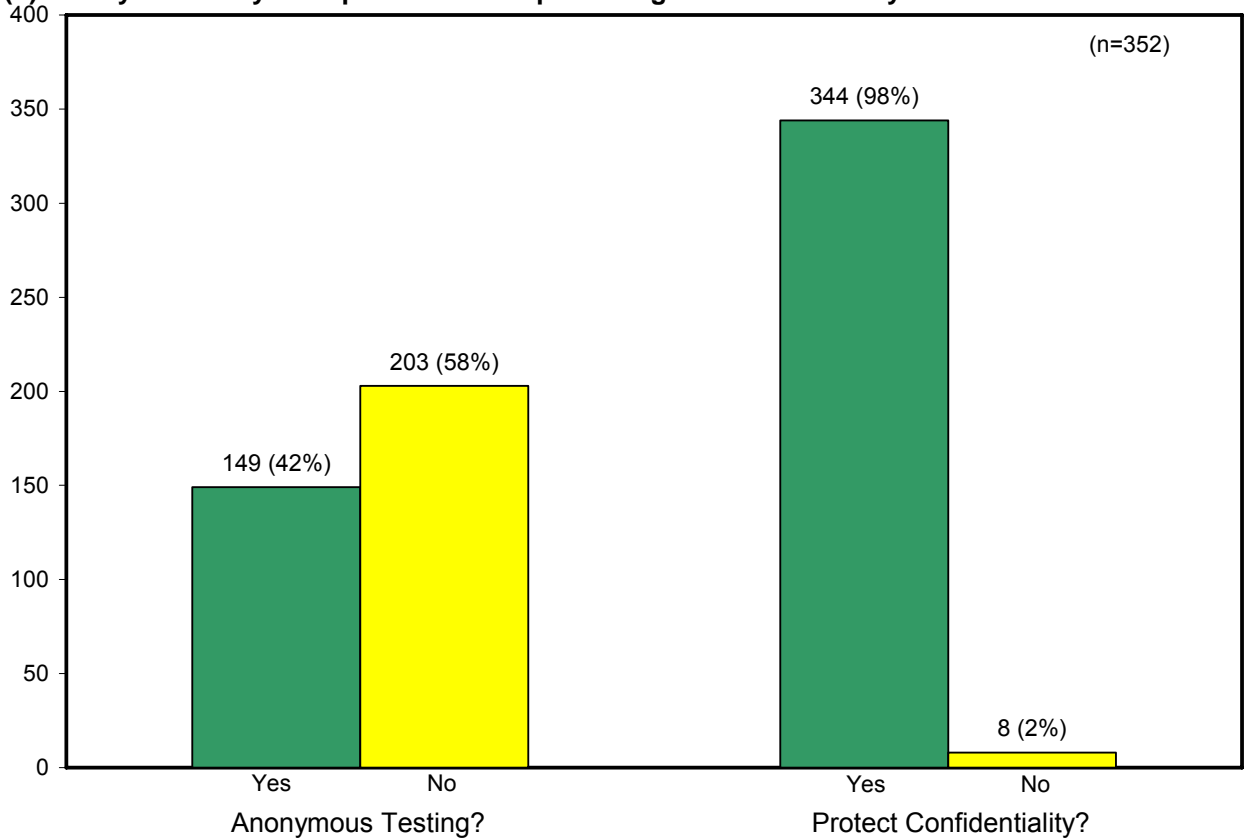
- Of the 212 labs that reported no preliminary positive HIV rapid tests (0% preliminary positive/reactive results) in the most recent representative month, 68% (144/212) performed less than 20 tests in that month.

- The facility types that had  $\geq 1\%$  initially reactive (preliminary positive) HIV rapid tests in the most recent representative month are listed below, by number and percentage of sites responding to the survey.

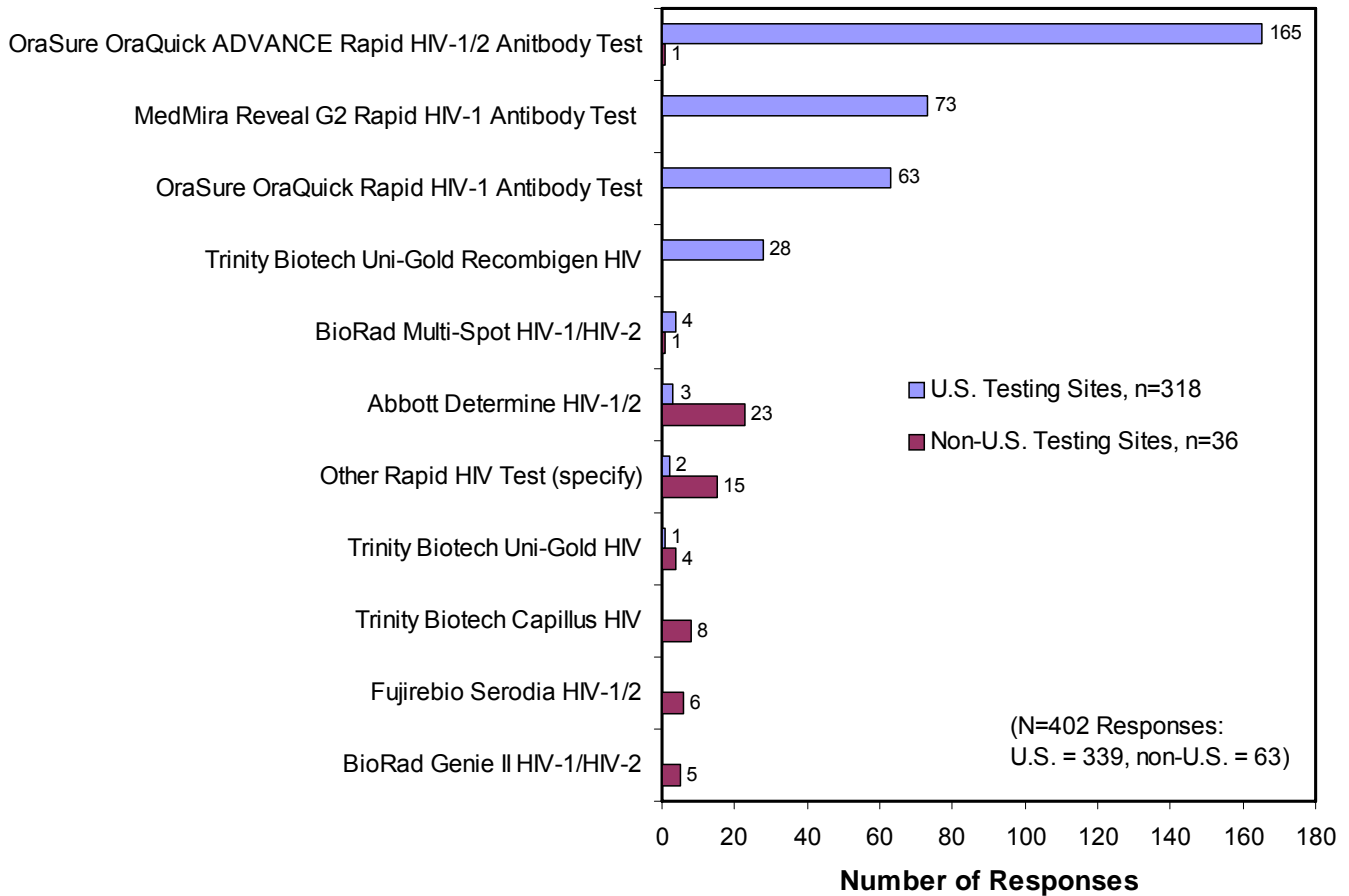
- Hospitals: (18%, 34/190)
- Health departments: 47% (23/49)
- Counseling and Testing sites: 68% (15/22)
- Physician Office: 40% (4/10)
- Independent facilities: 20% (2/10)
- STD Clinic: 86% (6/7)
- CBO: 68% (21/31)
- “Other”: 35% (6/17)
- Family Planning Center: 50%(1/2)
- Blood Bank: 38% (3/8)

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

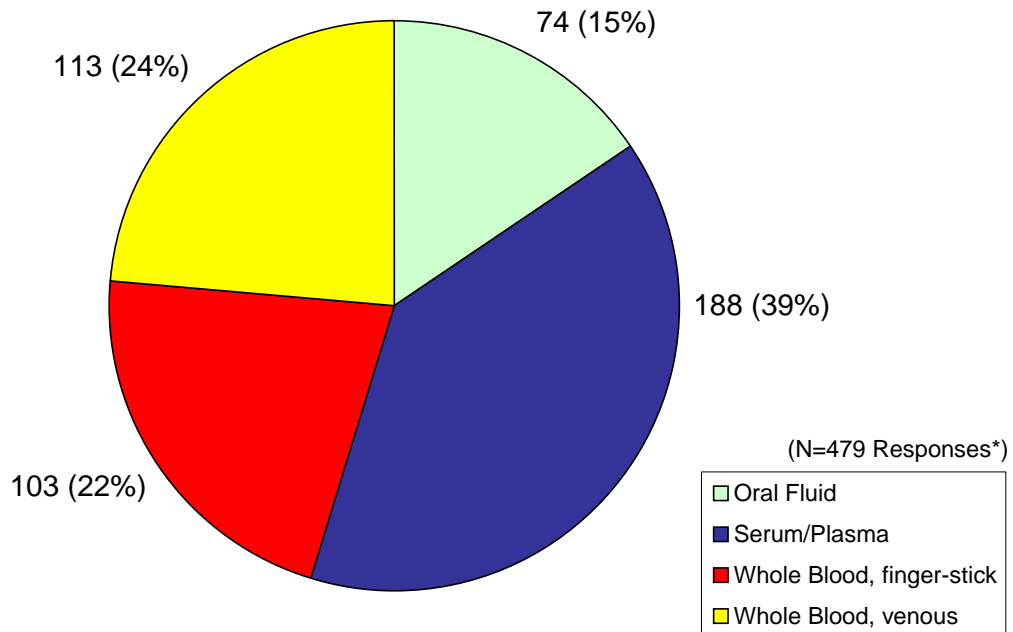
(b) Does your facility have procedures for protecting the confidentiality of HIV results?



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.)

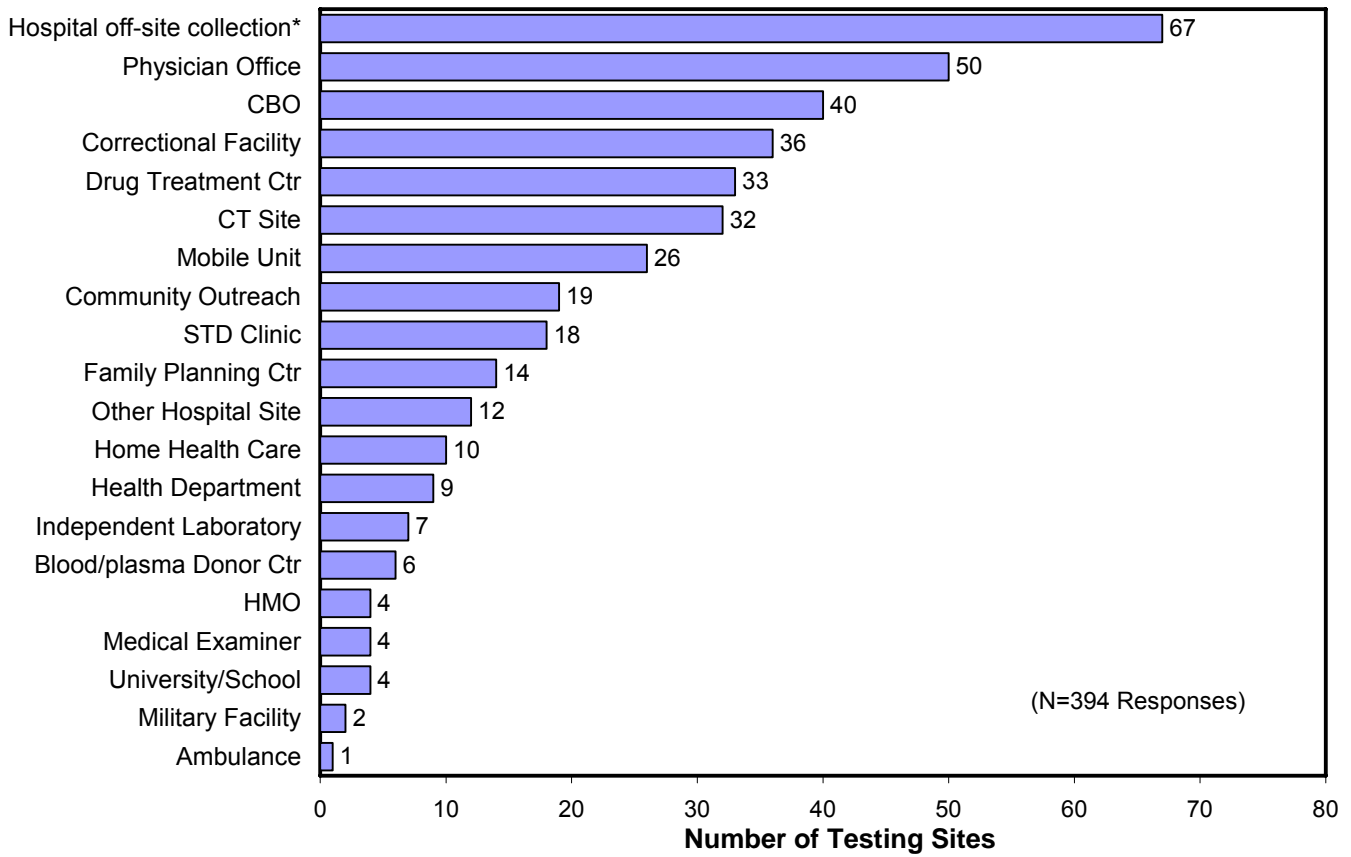


\*One facility (1/479, 0.2%) indicated using dried blood spots for their sample type. This facility indicated using Bio-Rad Genie II HIV-1/HIV-2 and Immunocomb HIV-1/2 test kits.

Number of respondents using the various sample types	Total
Serum/Plasma	152
Whole blood (venous)	54
Oral fluid and Whole blood (finger-stick)	36
Whole blood (finger-stick)	21
Whole blood (finger-stick) and Whole blood (venous)	20
Oral fluid	19
Serum/Plasma, and Whole blood (venous)	15
Oral fluid, Whole blood (finger-stick) and Whole blood (venous)	8
Serum/Plasma, Whole blood (finger-stick) and Whole blood (venous)	8
Serum/Plasma, Oral fluid, Whole blood (finger-stick) and Whole blood (venous)	6
Other combinations of sample types	8
Total	347

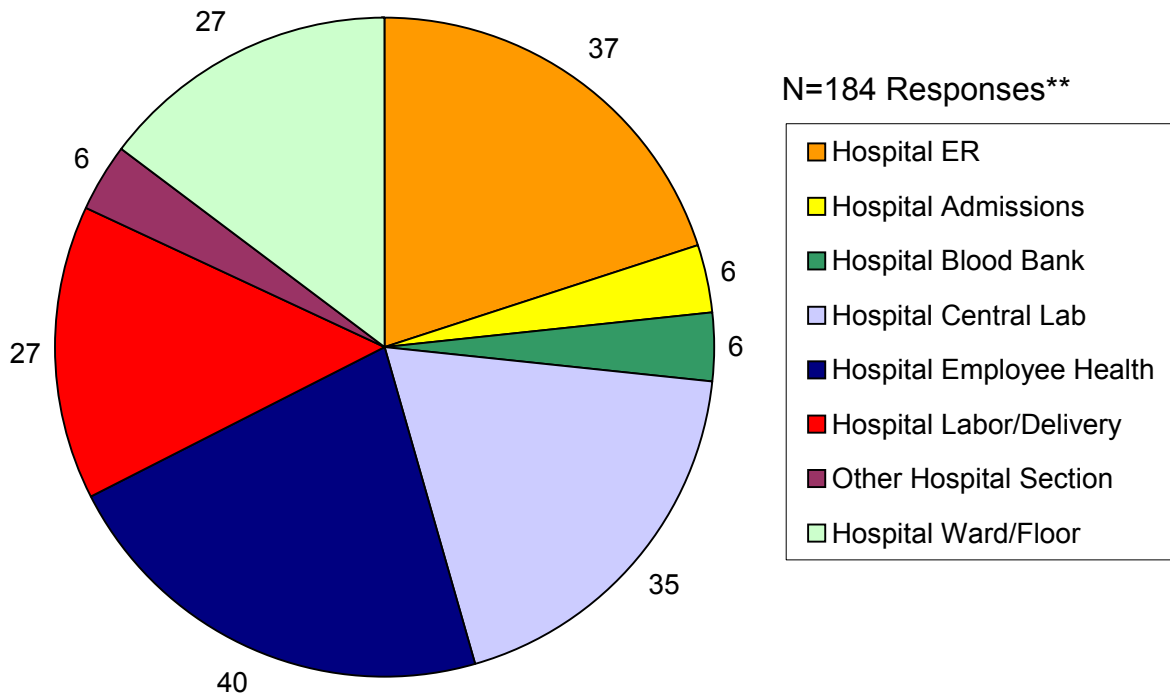


**7.(b) If you perform HIV rapid testing on specimens collected off-site, please indicate where they are collected. (Check all that apply.)**



**\*Specific Off-site Hospital Collection Locations (Check all that apply.)**

Note: Location other than where HIV test is performed



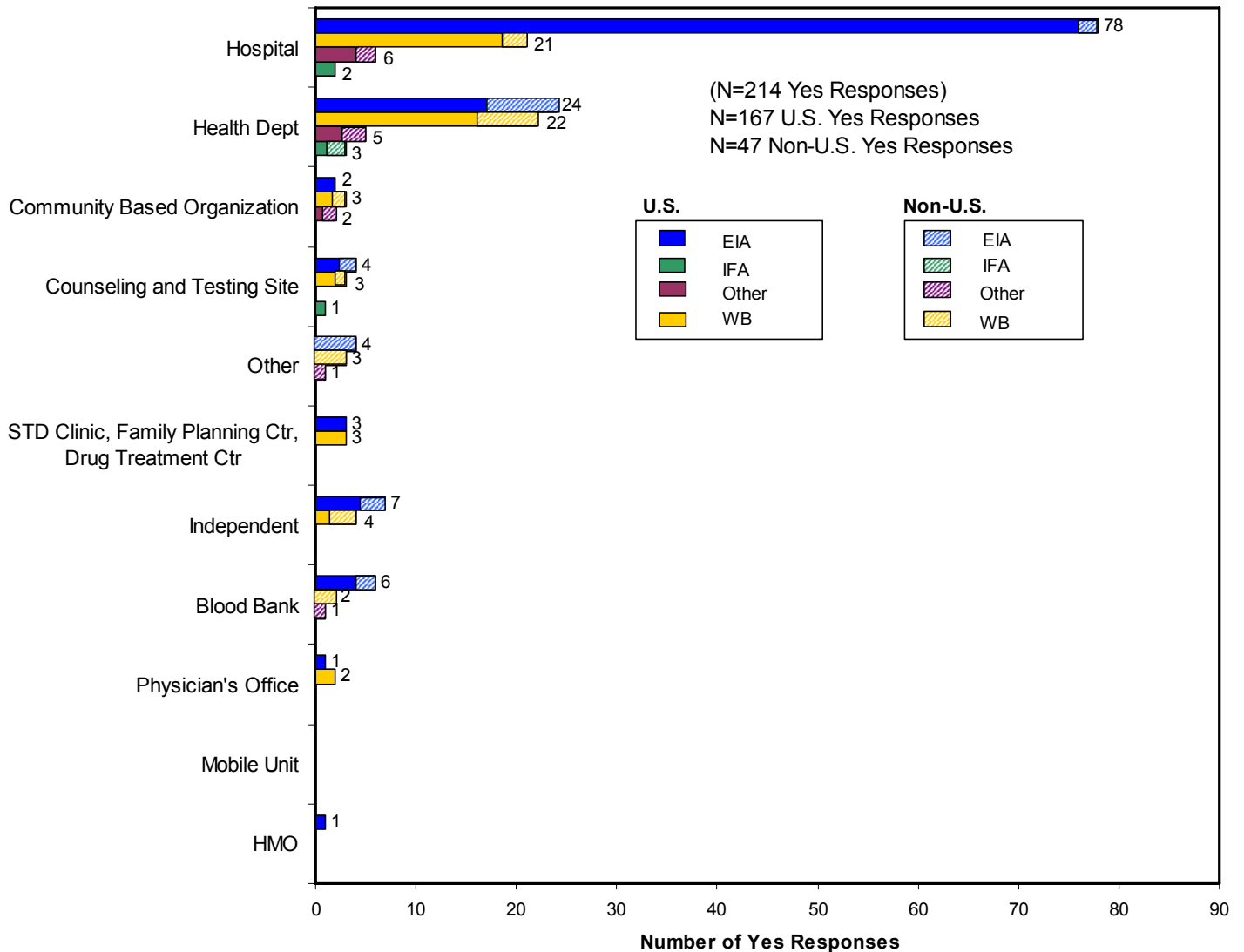
\*\* This represents multiple responses from hospital participants



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.)

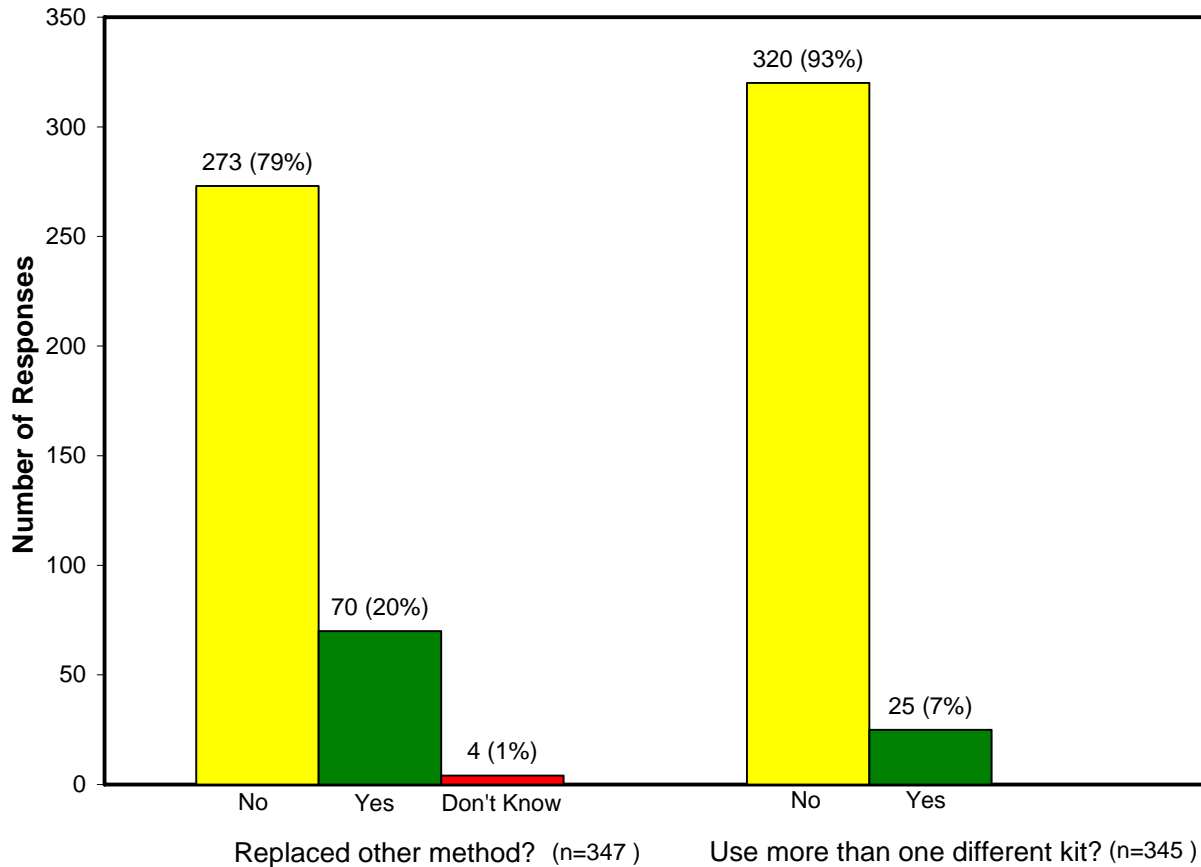
Responses	Total
No	200
Yes	143

Other HIV tests performed, by facility type



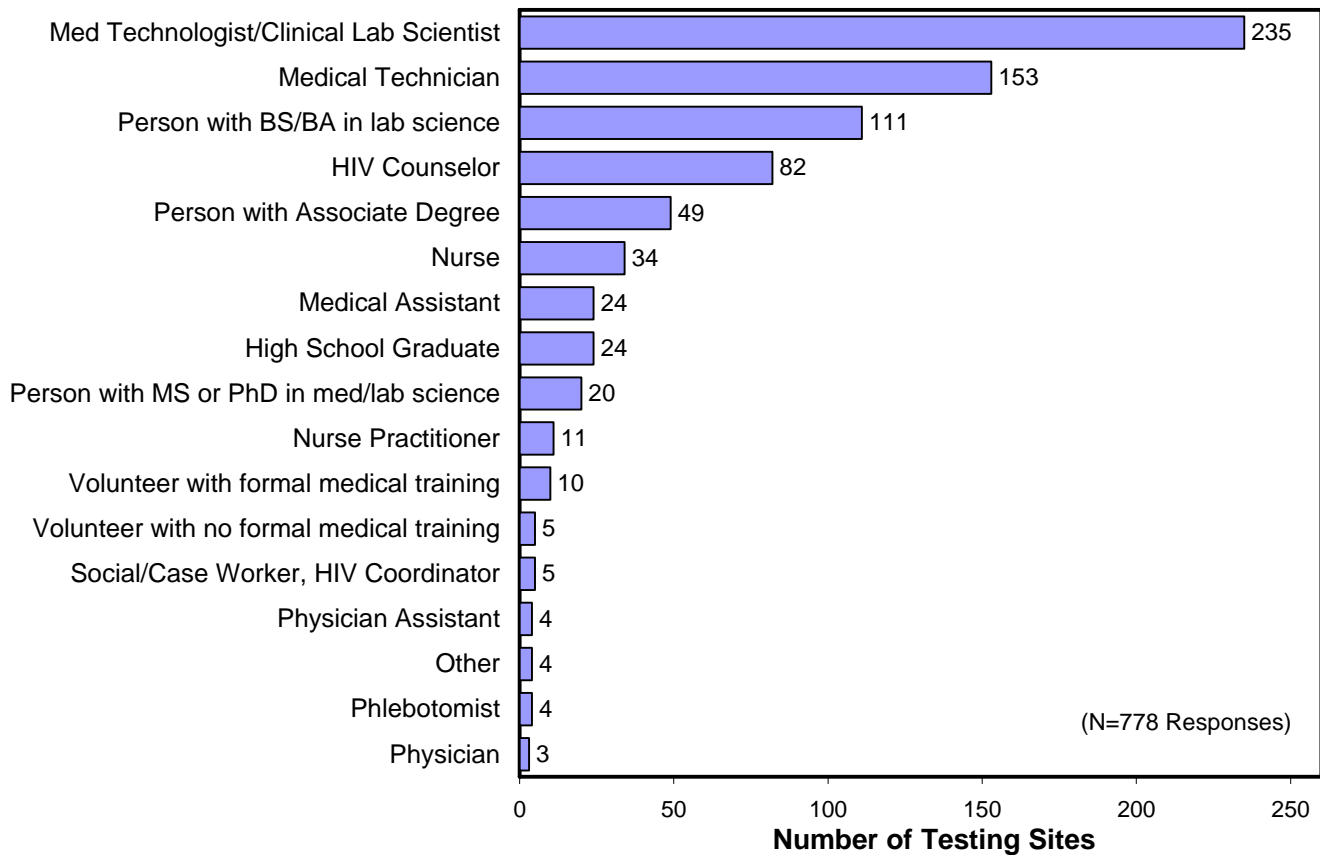
9.(a) Has HIV rapid testing replaced some other method of HIV testing in your facility?

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



- Of the 25 facilities that specified that more than one different HIV rapid test kit was used,
  - 19 were non-U.S. facilities, and
  - 6 were U.S. facilities.
- Of the 70 facilities that specified HIV RT replaced some “other” test,
  - 24 of those replaced were specified as EIA methods,
  - 31 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
  - 11 had other responses.

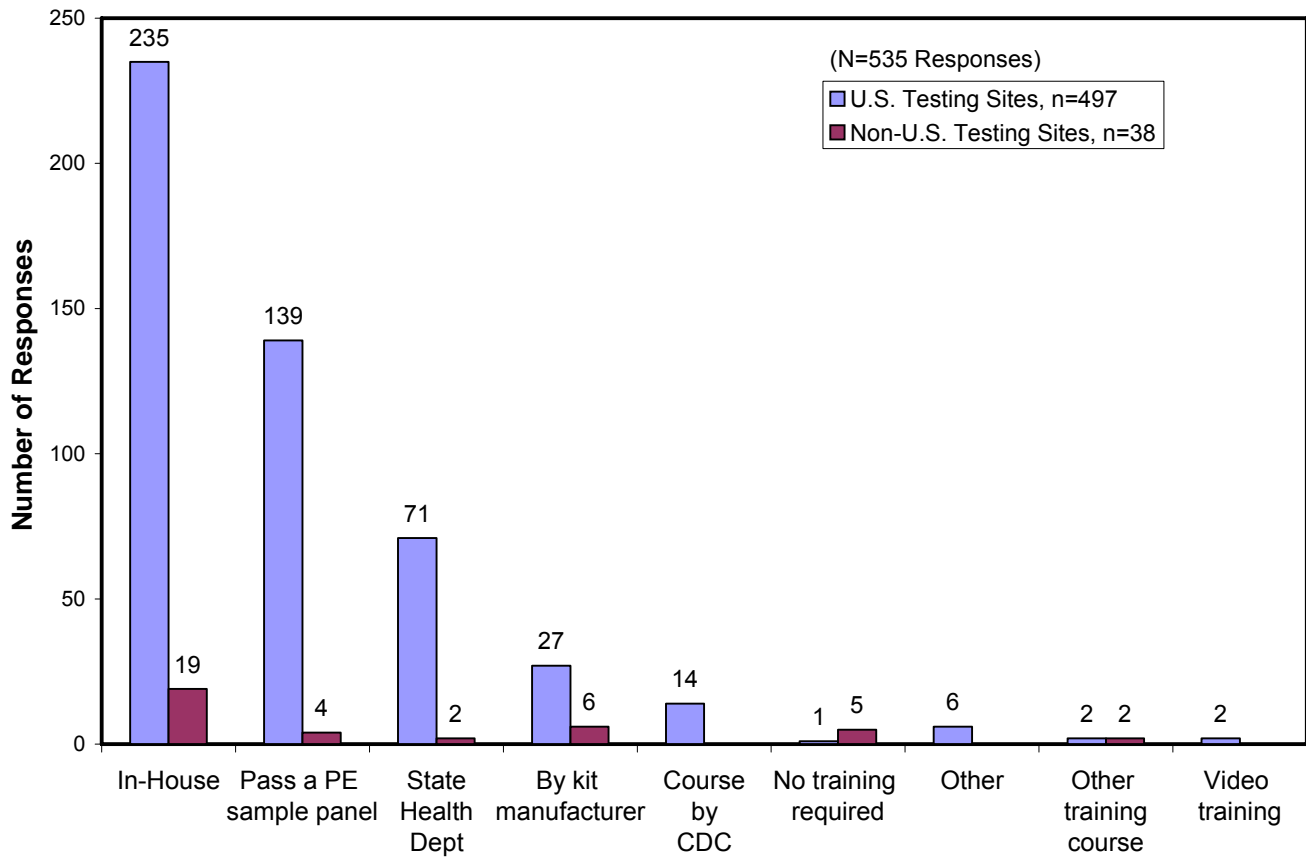
**10. Who performs HIV rapid testing in your facility on a regular basis? (Check all that apply.)**



The majority (87%, 391/448) of responses from hospitals, blood banks, 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% (366/417 responses)
- Blood Bank: 77% (10/13 responses)
- Independent: 83% (15/18)

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

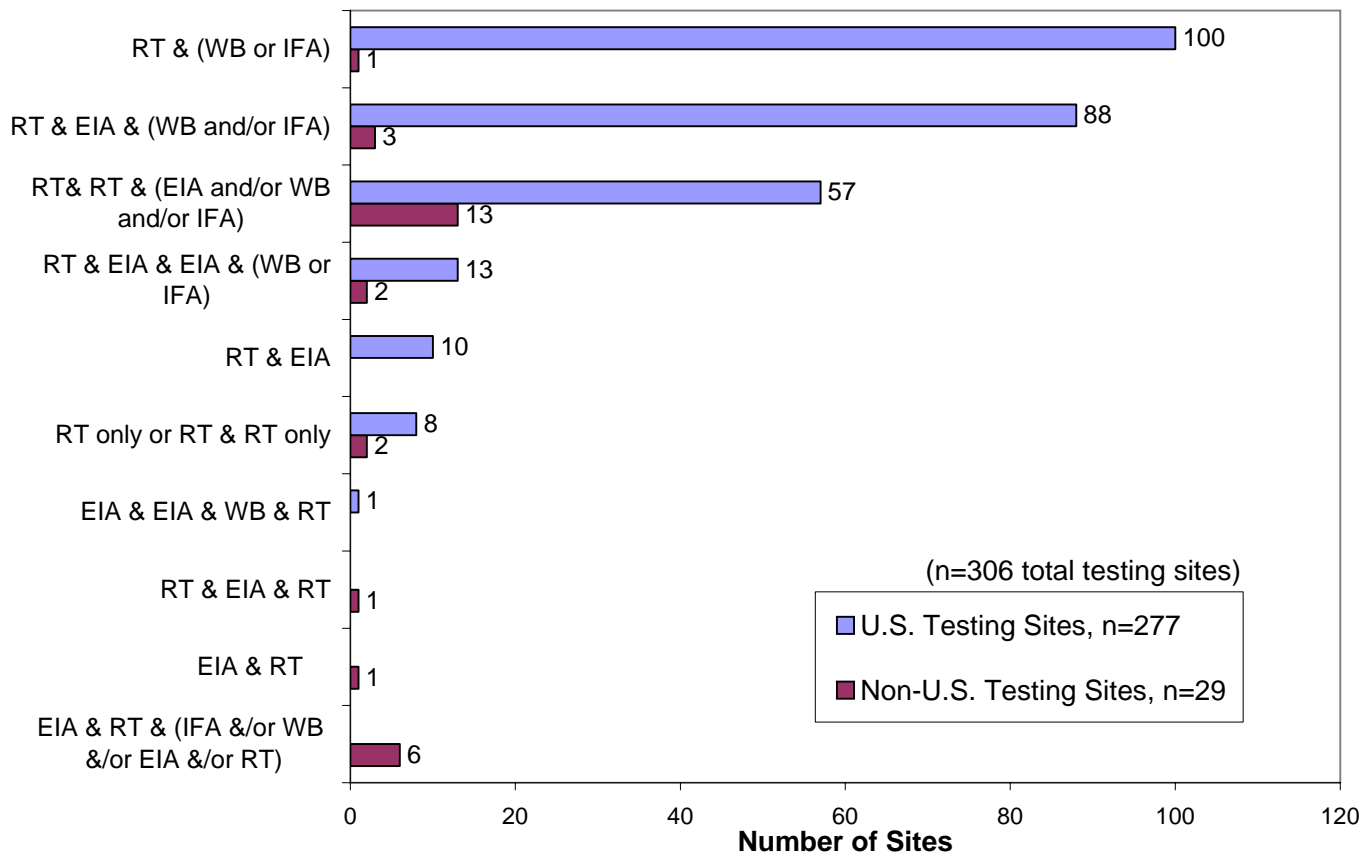


Training Type	# of Responses (N=)	95% Response Range	Median
In-house	224	0.5-40 hours	2 hours
Sample Panel Evaluation	134	1-10 samples	5
Health Department	67	2-72 hours	8 hours
By Kit Manufacturer	33	1-24 hours	4 hours
Centers for Disease Control and Prevention (CDC)	12	16-24 hours	24 hours

**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 (% Responses)
Hospital	182	5	187 (54%)
Health Dept	43	3	46 (13%)
Community Based Organization (CBO)	27	3	30 (9%)
HIV Counseling and Testing Site	22		22 (6%)
Other	16	1	17 (5%)
Physician Office	10		10 (3%)
Blood Bank	7	1	8 (2%)
Independent Laboratory	7	1	8 (2%)
STD Clinic	7		7 (2%)
Drug Use Treatment Center	4		4 (1%)
Family Planning Center	2		2 (<1%)
Mobile Unit	2		2 (<1%)
Health Management Organization (HMO)	1		1 (<1%)
<b>Totals</b>	U.S. sites = 301 Non-U.S. sites = 29 All sites = 330	U.S. sites = 10 Non U.S. sites = 4 All sites = 14	U.S sites = 311 (90%) Non-U.S. sites = 33 (10%) All sites = 344 (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?**



Some U.S. testing sites continue to use confirmatory testing algorithms that do not include Western blot (WB) or indirect immunofluorescence assay (IFA) as recommended by the CDC. U.S. participants are reminded that:

- 1) HIV rapid tests are screening tests and reactive results are considered to be “preliminary positives” that must be confirmed by either a WB or IFA test. (1,2)
- 2) EIA tests for HIV are also considered to be screening, not confirmatory, tests.
- 3) CDC Guidelines recommend that preliminary positive (reactive) HIV rapid tests be confirmed with WB or IFA, even if a subsequent EIA test is nonreactive. (1,2)

**References**

1. Quality Assurance Guidelines for Testing Using the OraQuick Rapid HIV-1 Antibody Test. Centers for Disease Control and Prevention, U.S. Dept. of Health and Human Services. 2003. [http://www.cdc.gov/hiv/rapid\\_testing/materials/QA-Guide.htm](http://www.cdc.gov/hiv/rapid_testing/materials/QA-Guide.htm)
2. Notice to Readers: Protocols for Confirmation of Reactive Rapid HIV Tests. MMWR 2004; 53(10): 221-222. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5310a7.htm>

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**

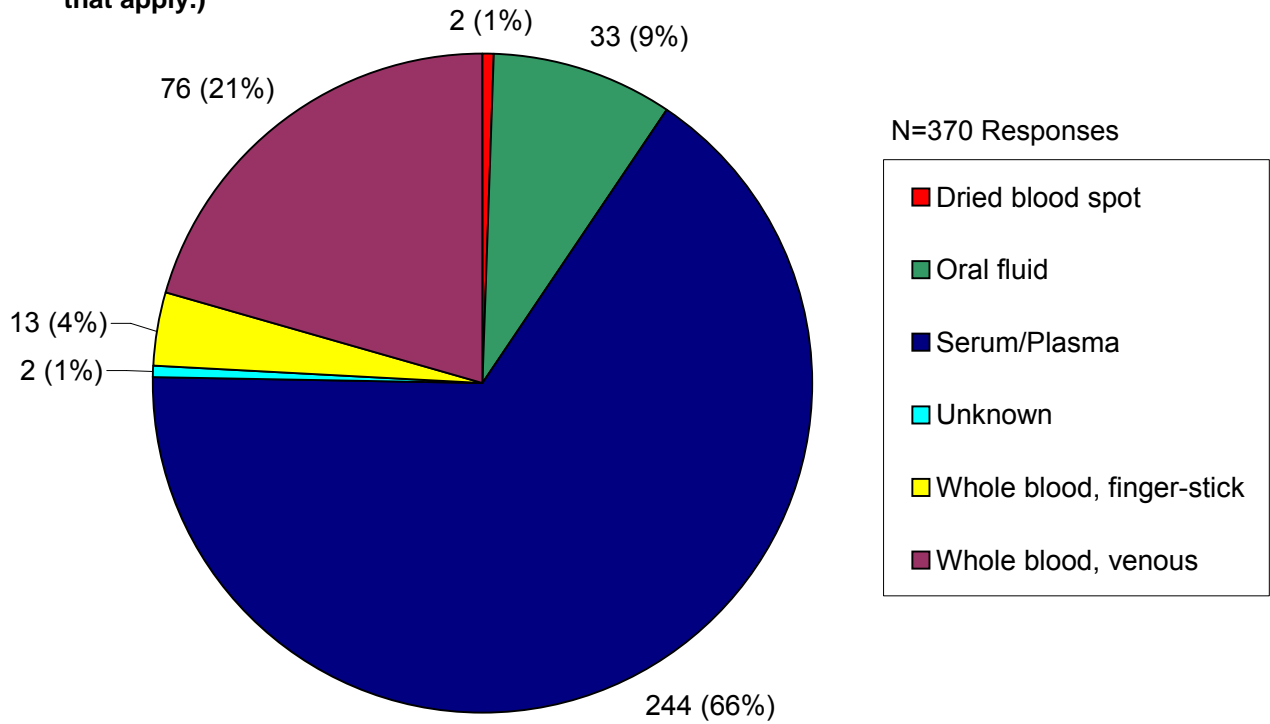
N=306

Step 1	Step 2	Step 3	Step 4	Step 5	Laboratory Responses			Percentage of Laboratories
					U.S. Sites	Non-U.S. Sites	Total Laboratories	
RT	WB				96	1	97	32%
RT	EIA	WB			70	3	73	24%
RT	RT	WB			28	5	33	11%
RT	EIA	IFA			16		16	5%
RT	RT/RT	WB			12	2	14	5%
RT	RT	EIA	WB		10		10	3%
RT	EIA				7	1	8	3%
RT	EIA	EIA	WB		5	1	6	2%
RT	RT				4	2	6	2%
RT	RT	EIA			3	2	5	2%
RT	RT/RT	EIA	WB		4		4	1%
RT					4		4	1%
RT/RT	EIA	WB			3	1	4	1%
RT/RT	WB				3		3	1%
EIA	RT	WB				3	3	1%
Other Algorithms								6%

**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.

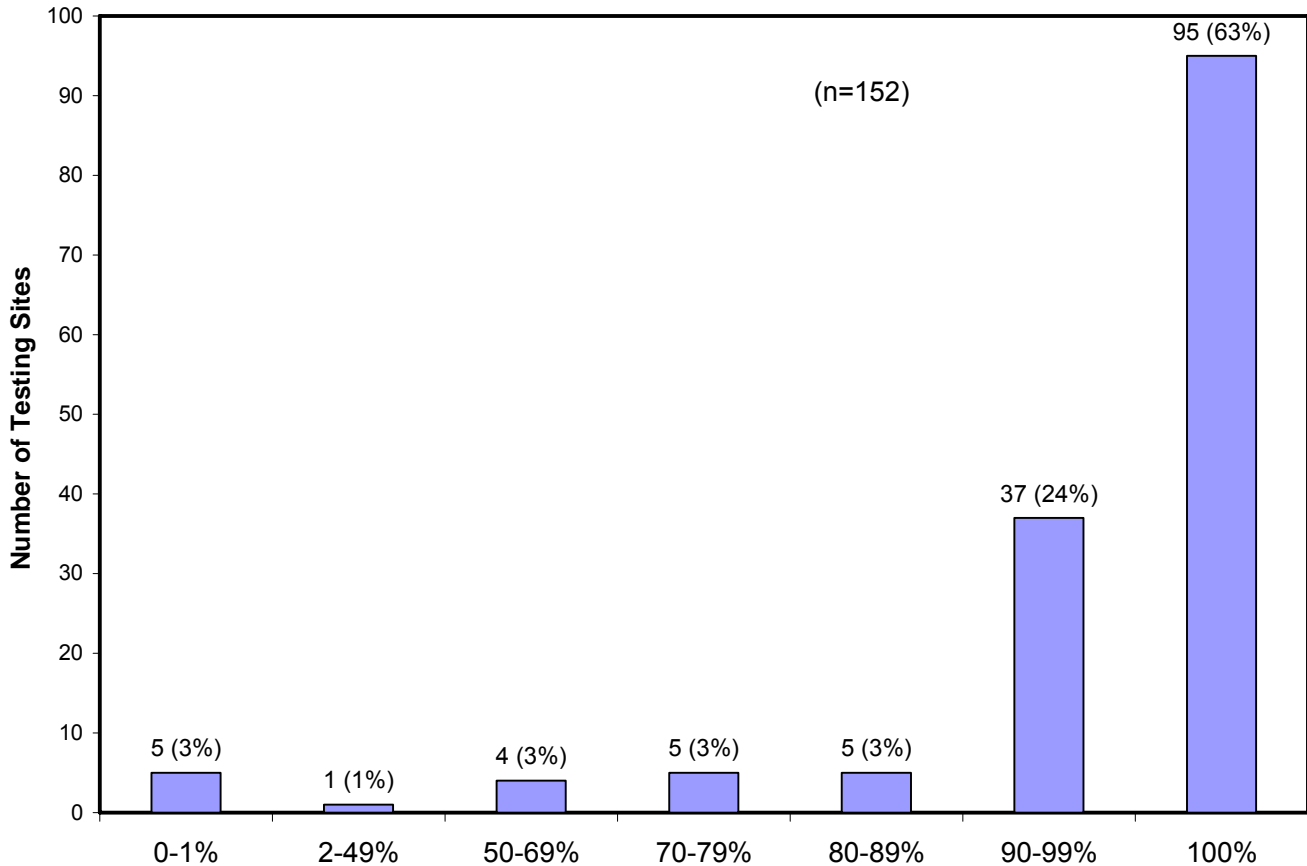
**Note:**  
Some facilities simultaneously (i.e. in the same Step) requested multiple tests be performed on samples sent out for HIV confirmation.

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



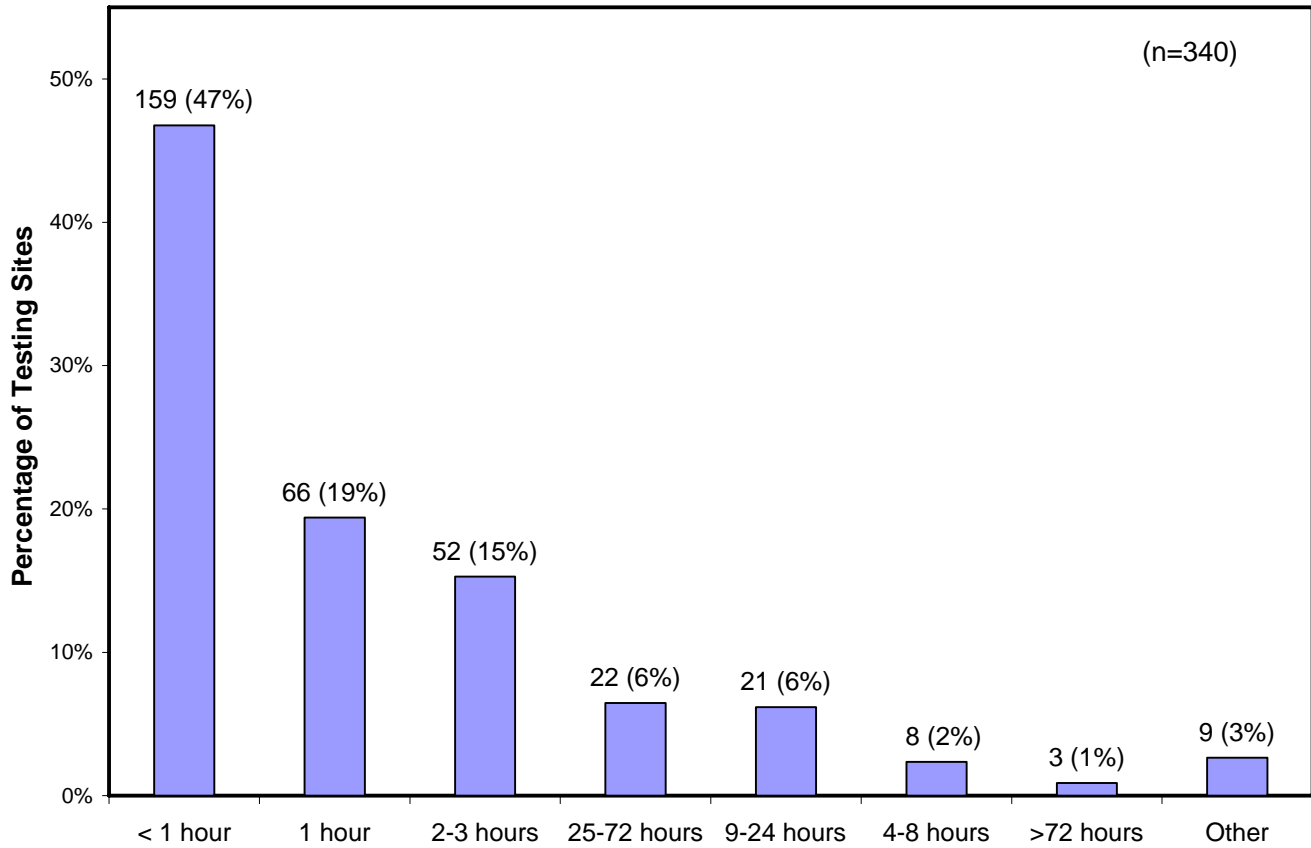
12. (d) Of the initially reactive (preliminary positive) HIV rapid test results for which a confirmatory test was performed, what percentage was confirmed as positive? (Please round off to the nearest whole percentage.)

Note: this figure is reflective of the most recent representative month



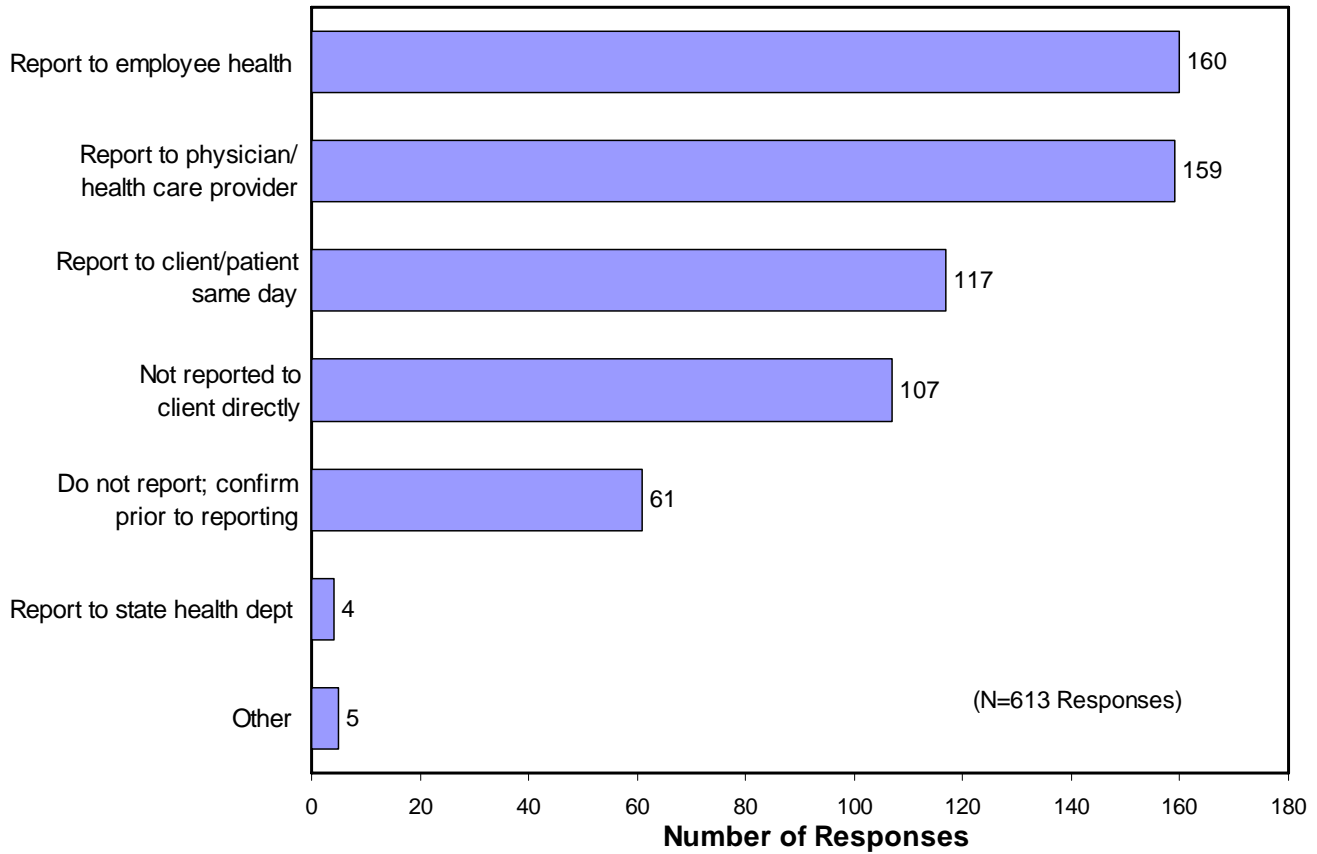


13. On average, how much time passes from collection of the specimen for HIV rapid testing at your facility until results are reported (given) to the client/patient? (Check only one.)

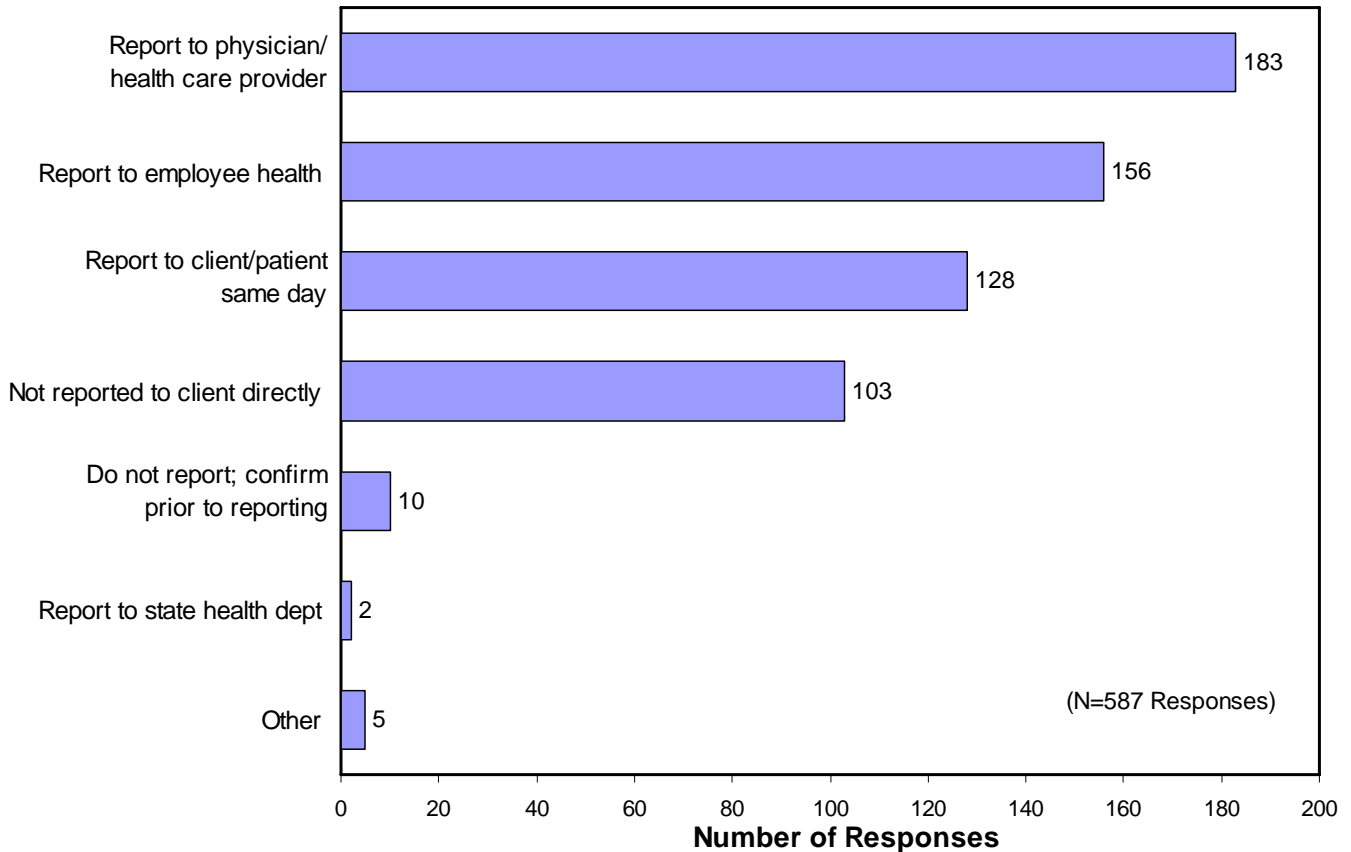


- Of the nine facilities that responded “other”:
  - three facilities indicated that it depends if test is STAT,
  - two facilities indicated it depends on the utilization of the test,
  - one facility indicated that they report out every shift,
  - one facility indicated they give results to the infection control RN,
  - one facility indicated reporting less than one hour for negatives and 25-72 hours for any reactive results, and
  - one facility provided no further detail.

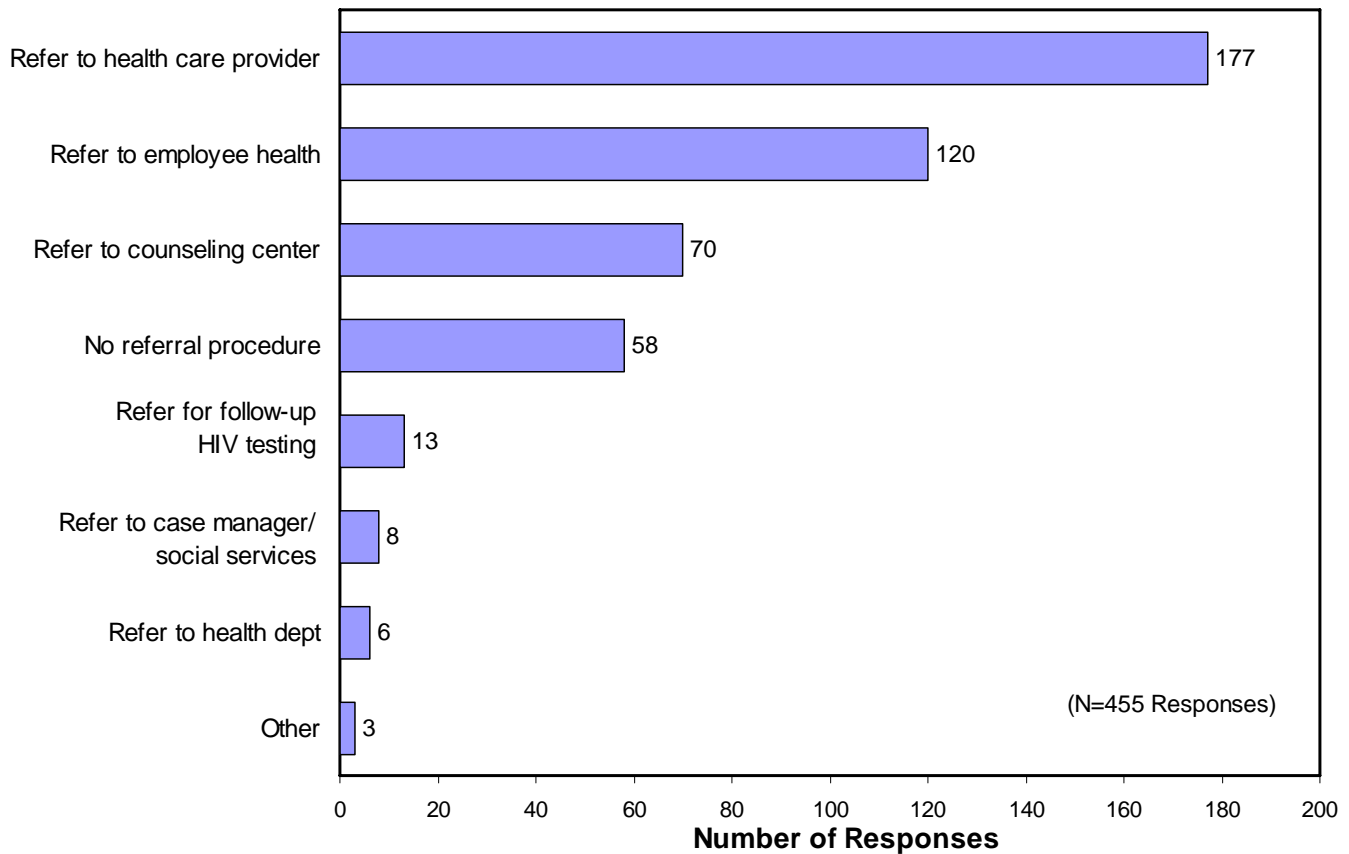
**14.(a) What is the typical reporting procedure to the client/patient for an initially reactive (preliminary positive) HIV rapid test? (Check all that apply.)**



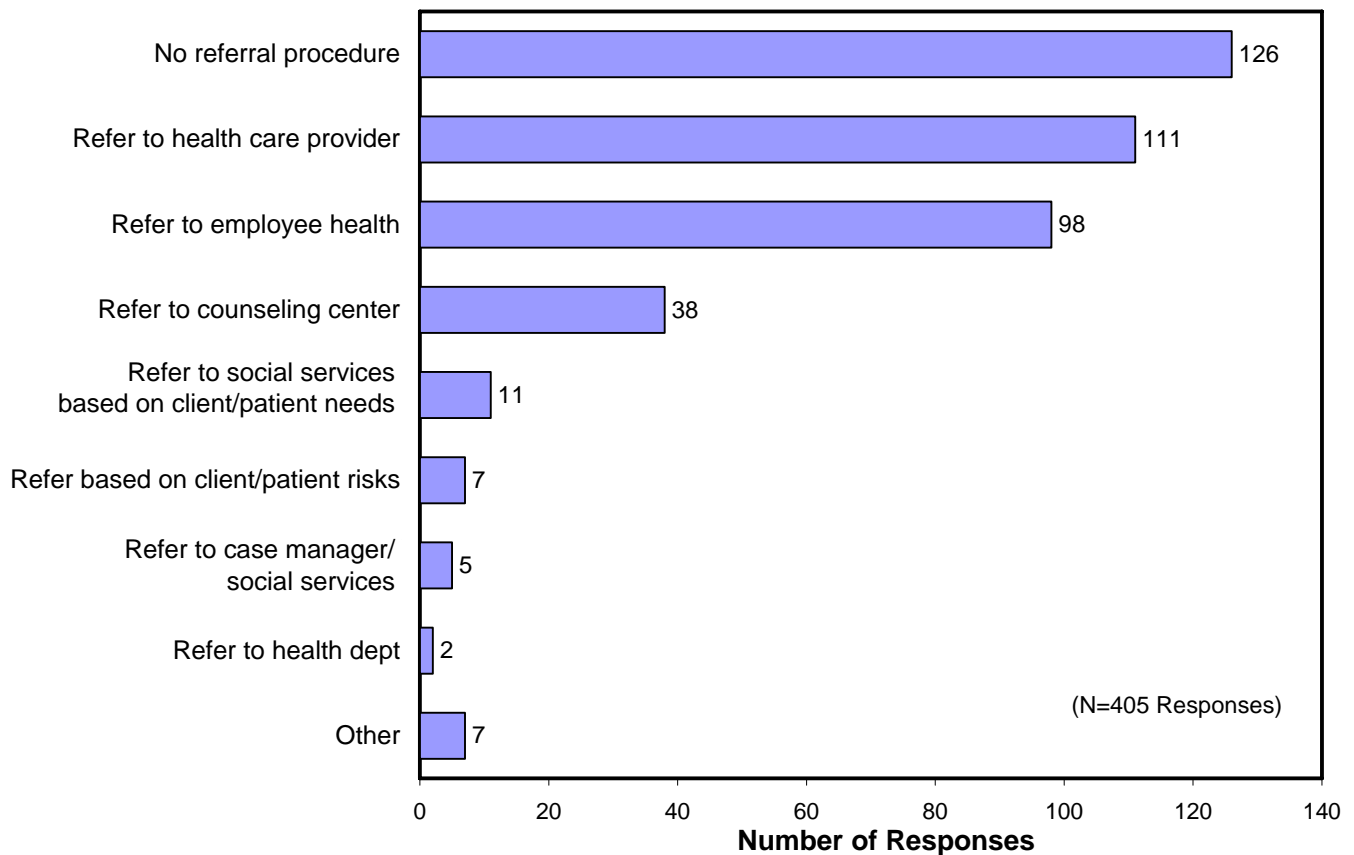
**14.(b) What is the typical reporting procedure to the client/patient for a negative HIV rapid test? (Check all that apply.)**



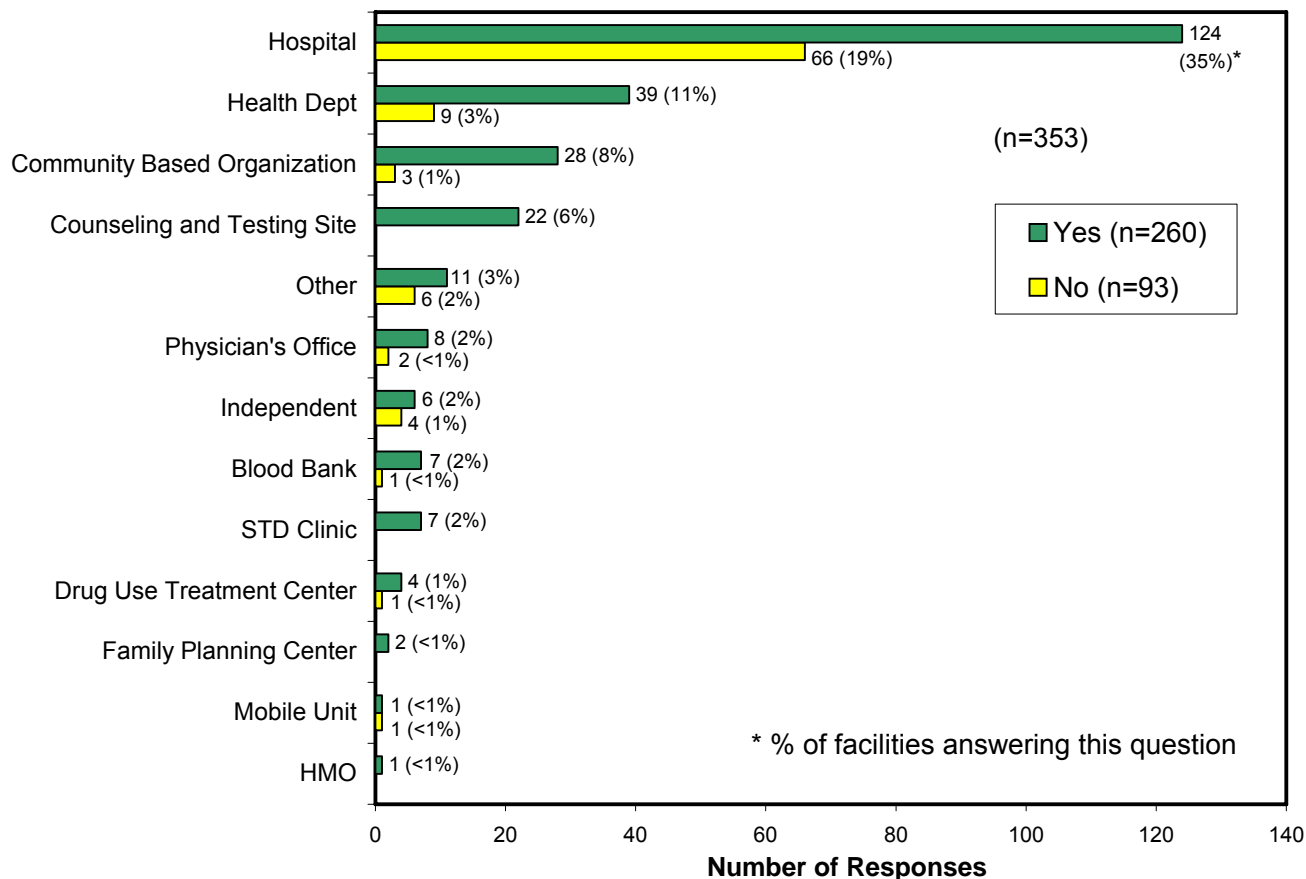
**14.(c) What is the typical referral procedure to the client/patient for an initially reactive (preliminary positive) HIV rapid test? (Check all that apply.)**



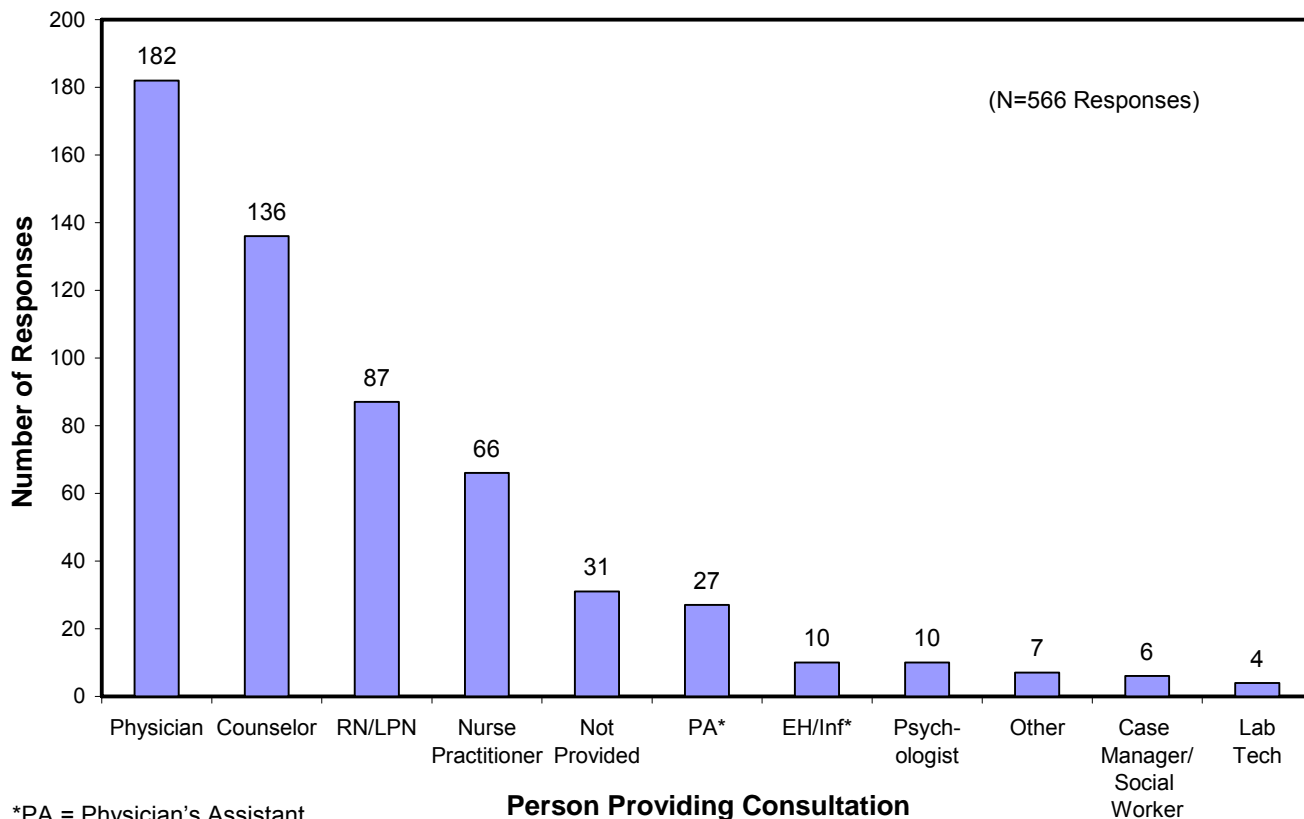
**14.(d) What is the typical referral procedure for the client/patient for a negative HIV rapid test? (Check all that apply.)**



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

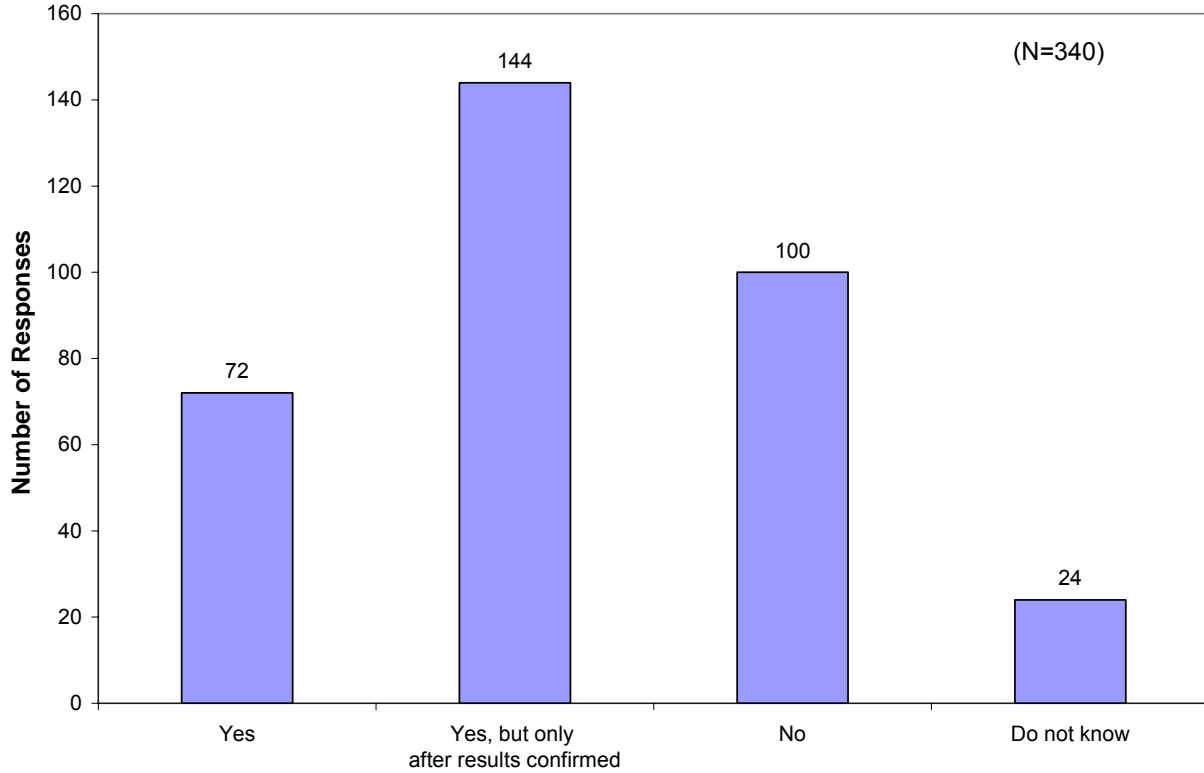


**14. (f) At your facility/testing site, who provides client/patient consultation for initially reactive (preliminary positive) HIV rapid testing results? (Check all that apply.)**

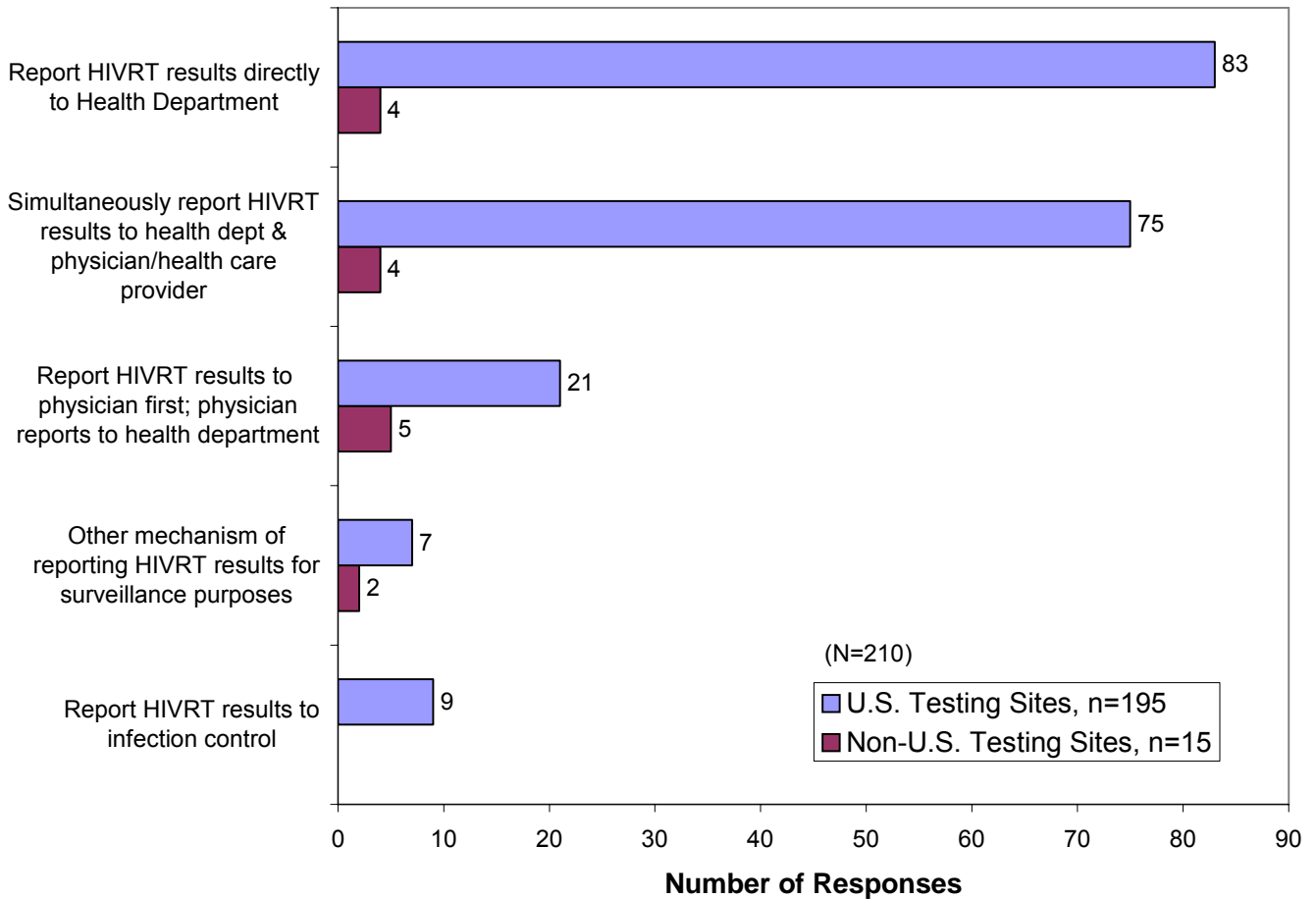


\*PA = Physician's Assistant  
EH/Inf = Employee Health, Infection Control

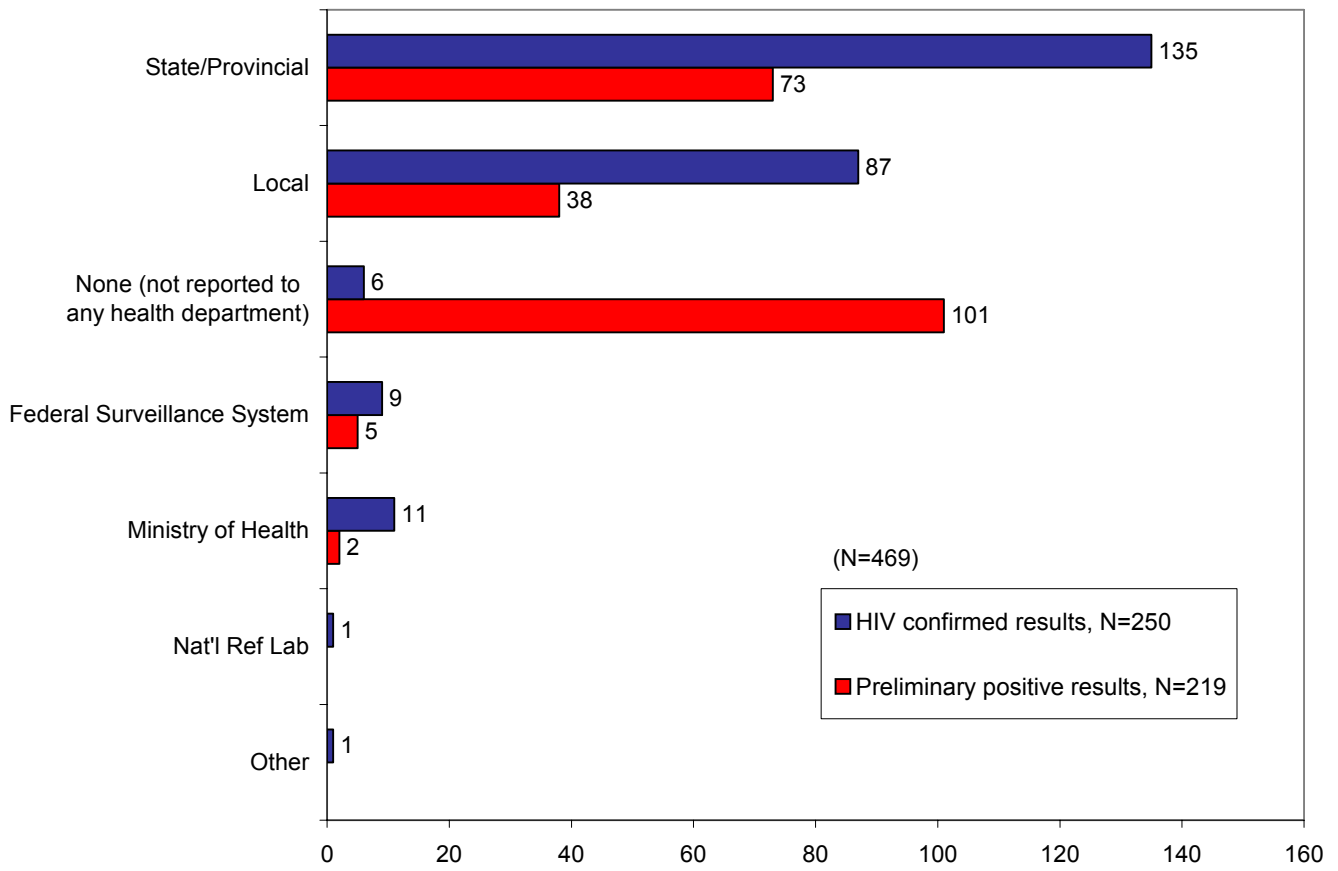
**15. (a) Is there a procedure at your facility to report reactive (preliminary positive) HIV rapid testing results to an outside entity for purposes of surveillance?**



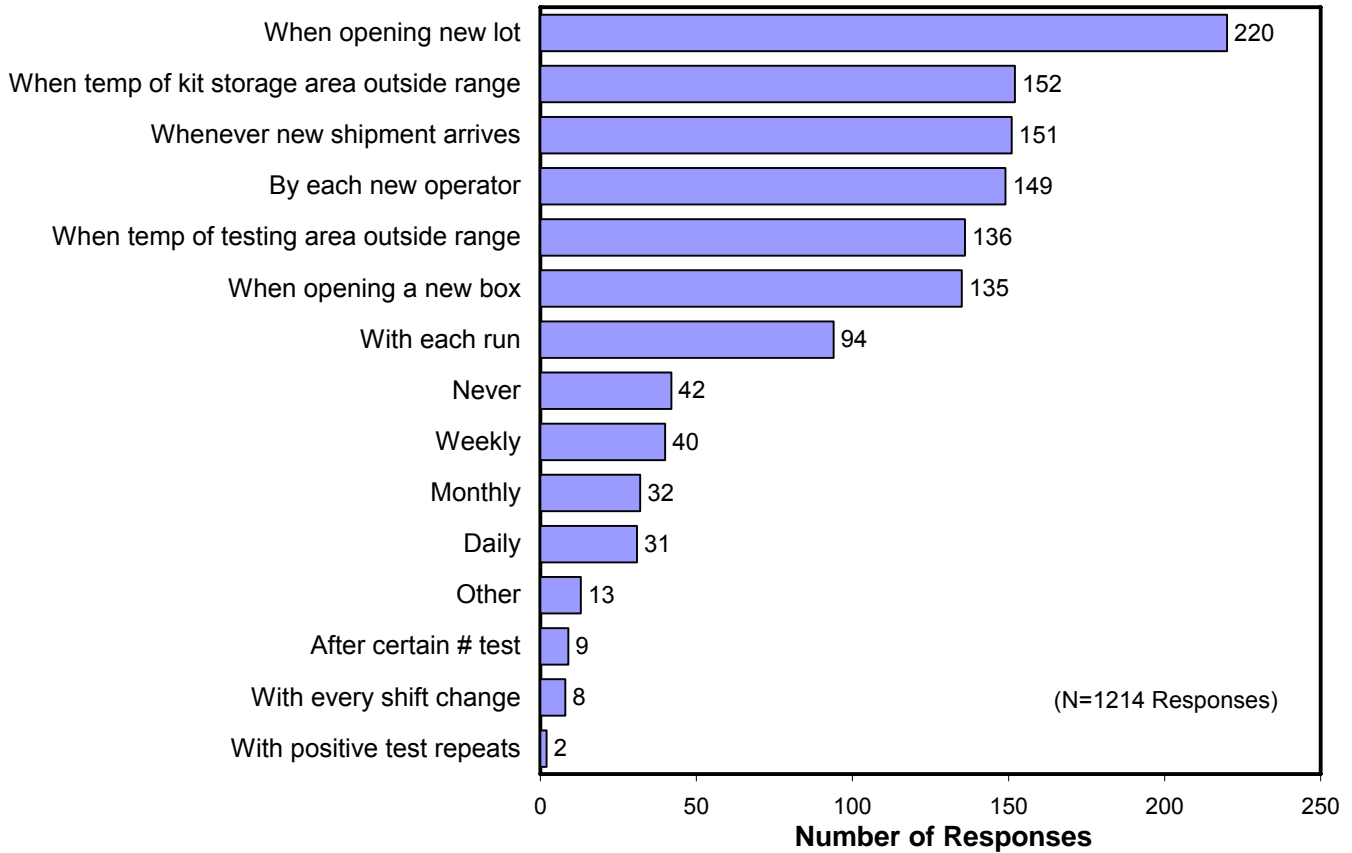
**15. (b) What is the typical HIV rapid testing results reporting procedure for the purposes of HIV surveillance? (Check one best answer.)**



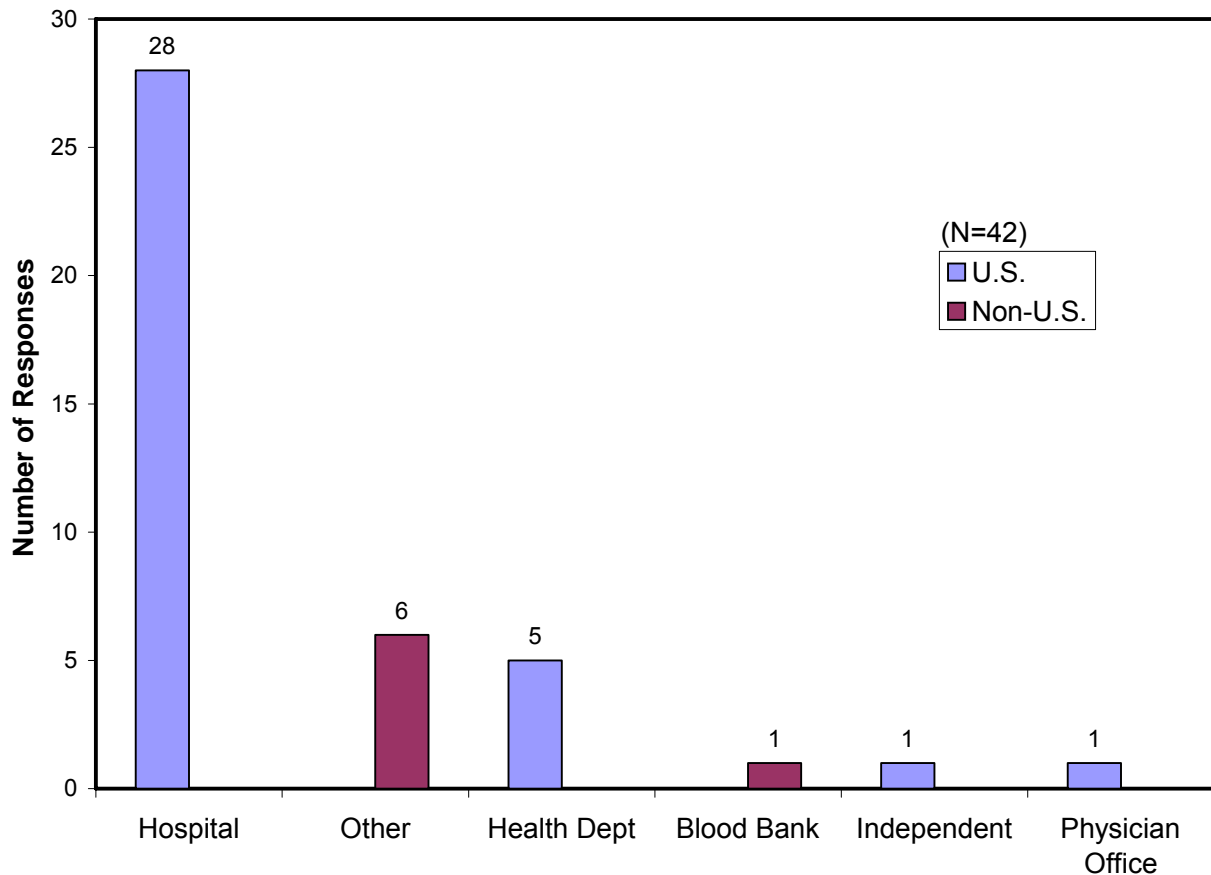
15. (c) To which health departments do you report HIV rapid testing results? (Check all that apply.)



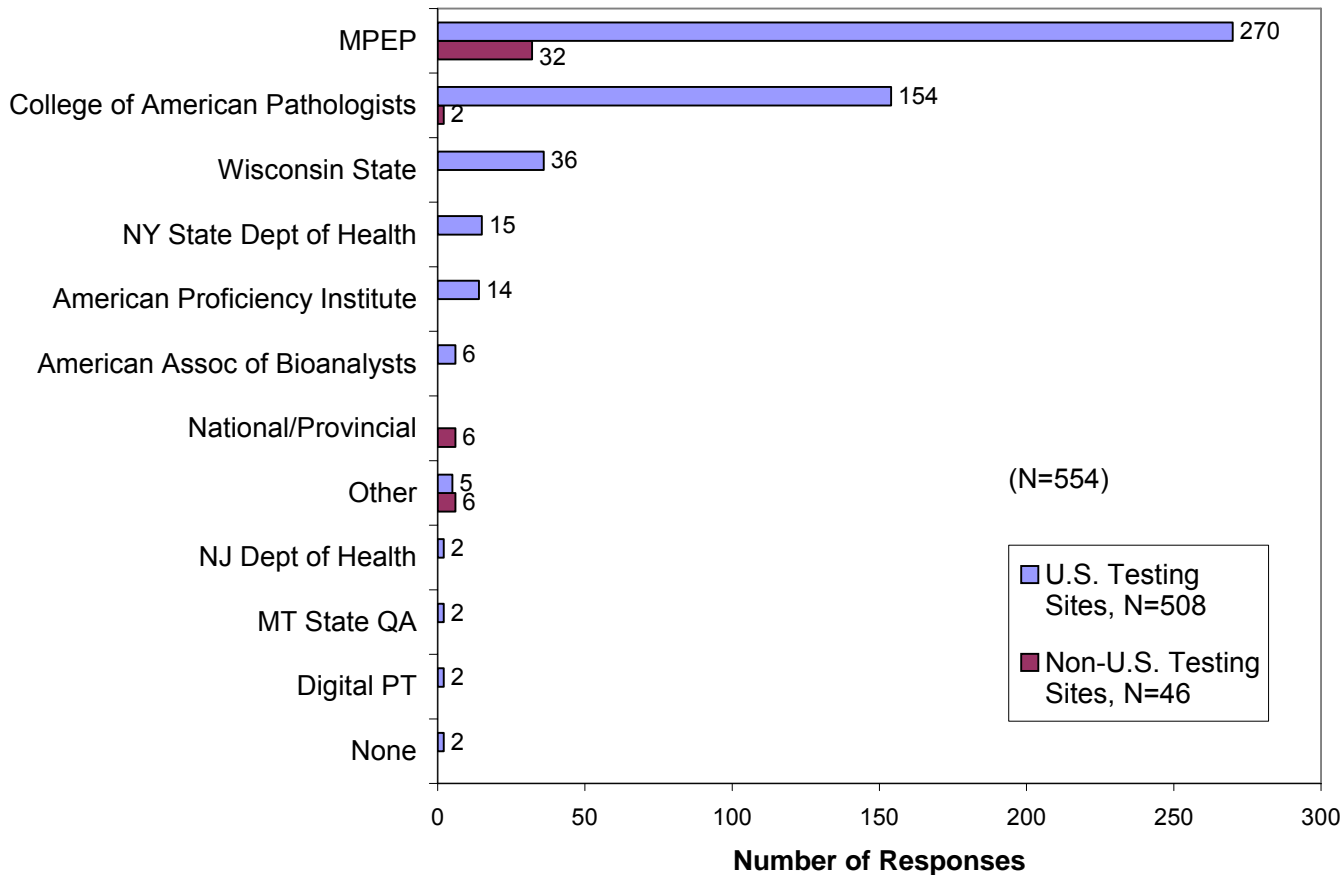
**16. How often does your facility/testing site run external controls (positive or negative controls not included in the test kit) when performing HIV rapid testing? (Check all that apply.)**



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

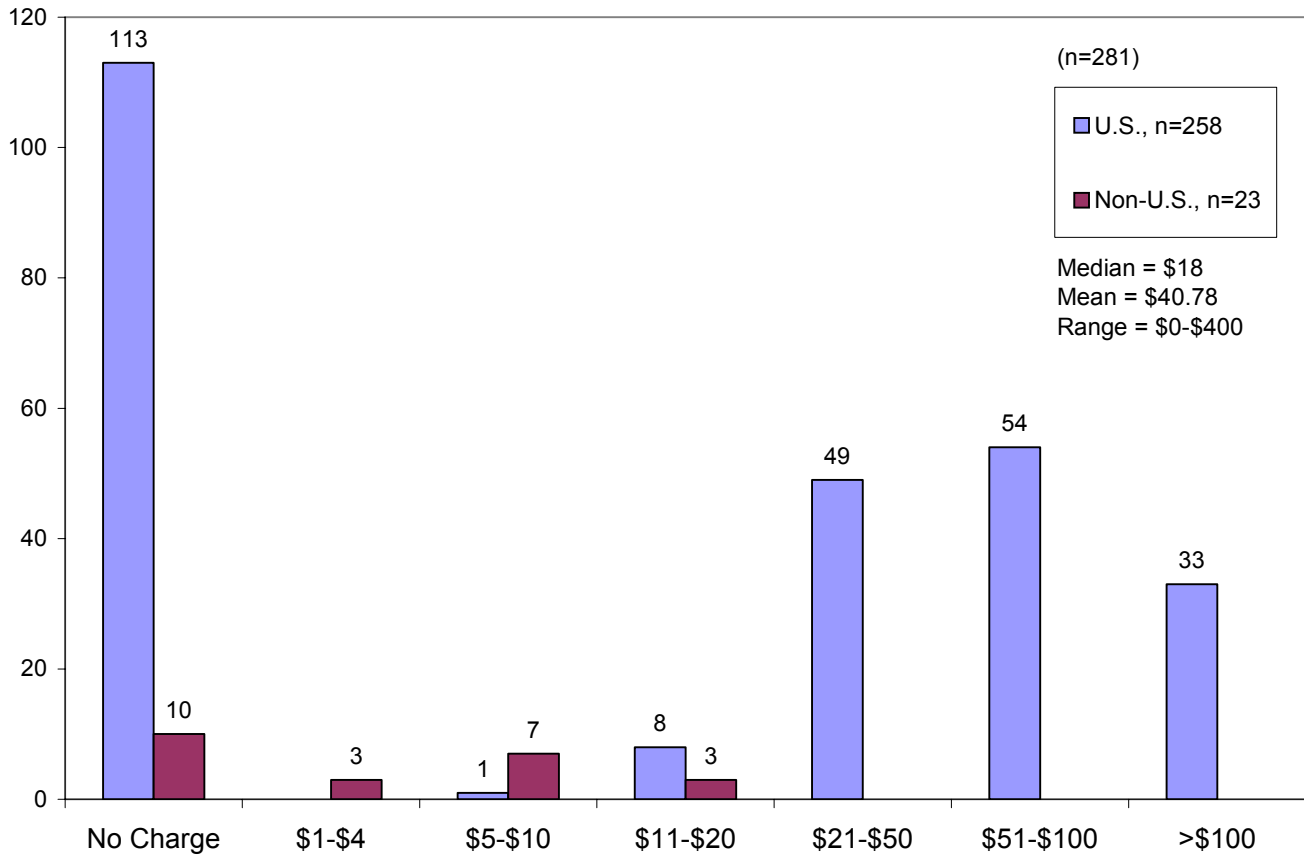


**17. In which external HIV proficiency testing (PT) or performance evaluation (PE) program(s) does your facility participate? (Check all that apply.)**





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



Many facilities (123/281, 44%) indicated that they do not charge for rapid tests. Two of these facilities indicate they do accept/and or encourage donations.

**18. Variable fee schedule**

Variable Fee Schedule	Total
Sliding Scale	8
Don't know, not specified	8
Varies with client category	6
<b>Total</b>	<b>22</b>

Only U.S. testing sites responded