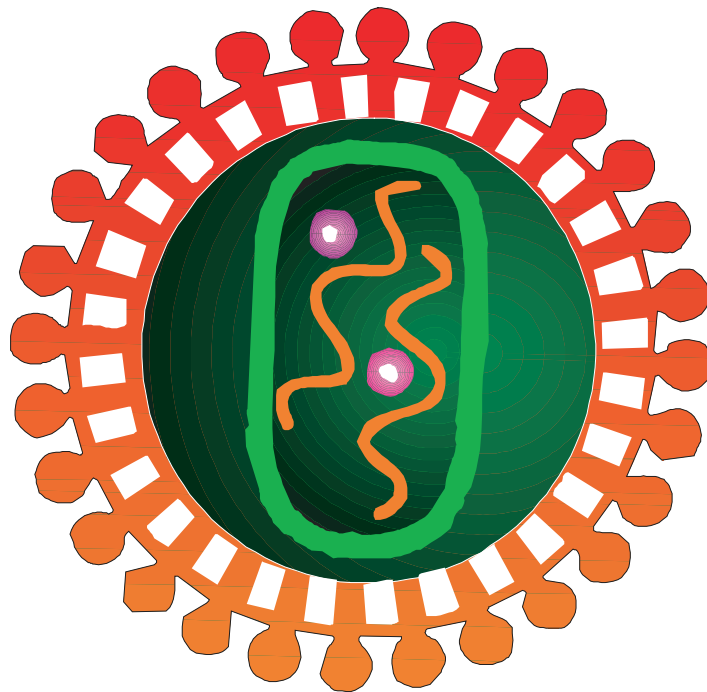




Questionnaire Results:
HIV Rapid Testing
Survey 2007



DEPARTMENT OF HEALTH & HUMAN SERVICES



HIV-1 Rapid Testing MPEP 2007 Survey Questionnaire Report of Results

Report of the August 2007 Human Immunodeficiency Virus Type 1 (HIV-1) Rapid Testing (RT) Performance Evaluation 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:

Division of Laboratory Systems..... D. Joe Boone, Ph.D., Acting 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).....G. David Cross, M.S., Manager
Laurina O. Williams, Ph.D., M.P.H.

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

MPEP acknowledges the contributions of Courtney Rodi, B.A., P.M.P. of Constella Group, LLC for her help in preparing this report.

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Contact information

Inquiries should be directed to the Model Performance Evaluation Program by calling Leigh Vaughan at (404) 718-1005 or emailing lvaughan@cdc.gov.

Summary of Results, HIV Rapid Testing Survey Questionnaire, August 2007

Purpose This report details the results from the CDC Model Performance Evaluation Program (MPEP) HIV Rapid Testing Practices Survey conducted during 2007.

Survey Description & Response Rate The HIV Rapid Testing Practices survey consisted of 22 multiple part questions. The questions covered topics over a variety of subjects related to HIV rapid testing, including:

- testing practices,
- testing site demographics
- personnel,
- quality assurance issues
- The survey was sent to all testing sites enrolled as of August 2007 in the MPEP HIV rapid (HIV-RT) testing program.
- Response rate: 46% (320/701), which included:
 - 295 U.S. testing sites and
 - 25 non-U.S. testing sites.
- Comparison to previous HIV Rapid Testing Questionnaire Survey (August 2005):
 - The distribution of respondents with respect to facility types compared with non-respondents was consistent across testing site types.
 - The number of participants who were mailed the current survey (701) was about a third greater than in the previous survey (520).
 - The response rate (46%) was lower than the previous survey (68%). This could be due to new sites being unfamiliar with the questionnaire process, or technical difficulties experienced with using the MPEP result website.

Survey Participants Data was collected regarding the survey participants, including: type of facility, areas of specimen collection & testing, as well as personnel experience & training

- **Facility types** (as self-identified in the survey and shown in Figure 1a) included:
 - 45% (144/319) hospital laboratories.
 - 41% (131/319) non-traditional or outreach testing sites, i.e. sites other than hospitals, HMOs, health departments, independent laboratories, reference laboratories, or blood banks.
 - For U.S. sites, these were primarily community based organizations (34/125), family planning centers (28/125), and HIV counseling & testing sites (24/125).
 - For non-U.S. sites, 24% (6/25) could be considered non-traditional sites, and included embassy health unit labs (2/6), and one each non-governmental organization, HIV counseling & testing site, physician's office and sexually transmitted disease clinic.
 - There was an increase in proportion of family planning centers in the U.S. (10%; 28/294), as compared to the previous survey (<1%; 2/318).

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Summary of Results, *continued*

Survey Participants, *continued*

- **Results for on-site and off-site specimen collection and testing locations** (Figure 7d) showed a variety of off-site locations, including:
 - CBOs (community-based organizations),
 - counseling and testing sites,
 - correctional facilities and
 - drug treatment centers.
 - **Testing personnel** data is shown in Figure 10. Persons performing HIV rapid tests were primarily:
 - medical technologists,
 - medical technicians,
 - HIV counselors,
 - persons with a BS/BA in a relevant science, and
 - persons with an associate's degree.
 - **Training** for HIV rapid tests is shown in graphs and tables 11a-d. The top three responses regarding type of training were:
 - 45% (220/488) in-house training,
 - 26% (127/488) required to pass a performance evaluation (PE) sample panel, and
 - 16% (79/488) state health department training.
-

Purpose of Testing

Survey questions collected information regarding HIV rapid testing purposes, target populations, and the cost of testing to the client/patient.

“Purpose of HIV rapid testing” data is shown in Figure and Tables 2a. In addition to the data shown, an analysis by facility type showed the following:

- Hospitals and health departments indicated that HIV rapid testing was being used for different purposes, including:
 - post-exposure treatment,
 - testing pregnant women,
 - voluntary HIV testing, and
 - initial screening for diagnosis.
 - Other facility types primarily indicated that HIV rapid testing was used for:
 - voluntary HIV testing,
 - testing all clients/patients seen in the facility, and
 - initial screening for diagnosis.
-

Target Population

Target population data is shown in Figures 2b and 2c. Participants were asked to note if they targeted any particular group for HIV rapid testing.

- Twenty-seven percent (80/291) of the sites selected a “high risk” target population, of these, 71 further identified one or more “high risk” categories for a total of 295 responses. The top three “high risk” response categories were:
 - gay/bisexual men or men who have sex with men (20%; 58/295),
 - injection drug users (20%; 58/295), and
 - high-risk women (e.g. sex workers (18%; 53/295).
 - Approximately half of the respondents (52%; 151/291) had no specific target population, i.e. they offered HIV rapid testing to the general population they serve. The majority of these testing sites (data not shown) were hospitals (72%; 109/151).
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Summary of Results, *continued*

Cost Re- imbursement

Cost reimbursement is described in Figure 21(a) and 21(b). Participants were asked to provide the approximate amount (in U.S. dollars) they charge to perform an HIV rapid test.

- Over half of respondents (57%, 132/232) indicated no charge for performing HIV rapid tests.
 - Thirty-eight percent (87/232) of the responding sites indicated that they charge amounts in excess of \$20.00. Of these,
 - 28% (24/87) charge between \$21 and \$50,
 - 46% (40/87) charge between \$51 and \$100, and
 - 26% (23/87) charge over \$100.
 - These were all U.S. sites
 - The sites were primarily hospitals (18/23) with the others being one each health department, blood bank, independent lab, community based organization and physician's office.
-

HIV Rapid Test Kits Used

HIV testing information includes the manufacturers and kit types selected by participants, as well as testing volume & result data.

HIV rapid test kits used by participants are shown in Figure 5, with 346 responses for kit type reported by 295 testing sites. Note: sites could select more than one kit type.

- The predominant kits reported by U.S. testing facilities were
 - OraQuick ADVANCE Rapid HIV-1/2 Ab tests (61%, 182/300),
 - Trinity Biotech Uni-Gold Recombigen HIV tests (15%, 46/300), and
 - MedMira Reveal G3 Rapid HIV-1 Ab tests (13%, 39/300).
- The predominant kit type reported by non-U.S. testing sites was Abbott Determine HIV-1/2 (74%, 17/23)
Note: a variety of kit types were reported by these testing facilities.

Nearly half (47%; 141/298) of the sites currently performing HIV rapid testing reported performing HIV tests other than rapid tests in their facilities. Sites could select more than one non-rapid HIV test response, and the majority of the 160 responses were made by:

- hospitals (39%; 63/160) and
 - health departments (28%; 45/160) (Figure 8).
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Summary of Results, *continued*

Test Volume & Results

For **test volume and result** data, see Figures 3b and 3c.

- The median number of HIV rapid tests performed in the most recent representative month calculated from the responses was 25, (range = 0 to 1400),
 - The highest volume sites are non-U.S. facilities, including the three sites reporting that they perform 1000 or more tests/month.
- A relatively high percentage of alternative* sites, family planning centers and counseling and testing sites performed 100 tests or more during the most recent month: 38% (5/13), 44% (4/9), and 48% (15/31), respectively).
- Most of the U.S. testing sites (66%; 173/263) reported that none of the HIV rapid tests performed on client/patient specimens in the most recent representative month was initially reactive (preliminary positive)

* Alternative sites include: HMO, medical examiner, STD clinic, correctional facility, drug treatment center and mobile units.

Confirmatory Testing

Confirmatory testing practices are depicted in Figures 12a through 12f.

- Most participants (93%; 272/291) reported that confirmatory testing was performed either within their facility or at another facility on initially reactive (preliminary positive) results,
 - specific testing algorithms are depicted in tables 12b and 12c.
 - 7% (19/291) answered “no” to this question, implying that no confirmatory testing was performed.
 - 8% (18/231) of 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.^{1,2}
-

Quality Control

Quality Control (QC) practices and sources of QC material are shown in the figures and tables 19a through 19b.

- 97% of the responses (1043/1072) indicated that external quality control samples (not included in the test kit) were run when performing HIV rapid testing.
 - This was the same proportion as the responses given in the previous (2005) survey (97%; 1172/1214).
 - Participants could give more than one response.
 - 3% of the responses (29/1072) indicated that external quality control samples (not included in the test kit) were never run, although it should be noted that most of these sites reported using test kits that had quality control material included in the kit.
 - Most of these were U.S. testing sites.
 - Testing QC samples as a part of an overall quality assurance system is recommended.¹
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Summary of Results, *continued*

Privacy Issues

Privacy issues (Figure 4a/b) were examined by asking sites if they provided anonymous HIV rapid testing or had confidentiality procedures.

- Less than half (42%; 120/289) of the testing sites that answered the question responded that they provide anonymous testing, while
 - Nearly 100% (99%; 286/289) responded that they do protect the confidentiality of the client/patient being tested for HIV.
-

Testing turn around time

The **time from specimen collection to the results** being given to the client/patient are depicted in the figures and tables for 13a & 13b, for both reactive (preliminary positive) and negative results.

- Reactive HIV rapid test reporting times included responses from 287 testing sites:
 - Most sites reported results in 1 hour or less (66%, 190/287).
 - Some (14%, 40/287) reported results between 1 to 3 hours.
 - A few (4%, 11/287) reported times of 24 hours or less.
 - Other sites (7%, 20/287) reported times between 25 and 76 hours.
 - The remaining sites (9%, 26/287) reported other time periods.
 - Negative HIV rapid test reporting times included responses from 290 testing sites:
 - Most sites reported results in 1 hour or less (72%, 210/290).
 - Some (12%, 36/290) reported results between 1 to 3 hours.
 - Other sites (7%, 20/290) reported times of 24 hours or less.
 - A few (4%, 11/290) reported times between 25 and 76 hours.
 - The remaining sites (4%, 13/290) reported other time periods.
-

Same day result reporting

Reporting of results within one day was examined for both reactive and negative HIV rapid test results in tables 14a-e through tables 15 a-e.

- A large majority of testing sites responding to the question (69%; 203/293) reported they give results of initially reactive (preliminary positive) HIV rapid test results the same day as testing;
 - virtually all of these sites (99%; 201/203) also give negative test results the same day as testing.
 - Of those labs that do NOT give the results of initially reactive (preliminary positive) HIV rapid test results the same day, about half (51%; 31/61) also did not report results of negative results the same day.
 - This appeared consistent over type of facility.
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Summary of Results, *continued*

Additional comments

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.

- 1) Recommendations for an overall quality assurance program for HIV rapid testing sites and for good laboratory practices can be found on the MPEP website: <http://wwwn.cdc.gov/mpep/default.aspx>
- 2) 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) This and other links to useful information about HIV rapid testing, as well as other HIV testing issues, can be found at:
 - o <http://www.cdc.gov/hiv/topics/testing/rapid/index.htm> and
 - o <http://www.cdc.gov/hiv/topics/testing/guideline.htm>

References

- 1) Quality Assurance Guidelines for Testing Using Rapid HIV Antibody Tests Waived Under the Clinical Laboratory Improvement Amendments of 1988: http://www.cdc.gov/hiv/topics/testing/resources/guidelines/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.cdc.gov/mmwr/preview/mmwrhtml/mm5310a7.htm>
- 3) CDC. Good Laboratory Practices for Waived Testing Sites, MMWR Recommendations and Reports. 2005; 54(RR13); 1-25. <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5413a1.htm>

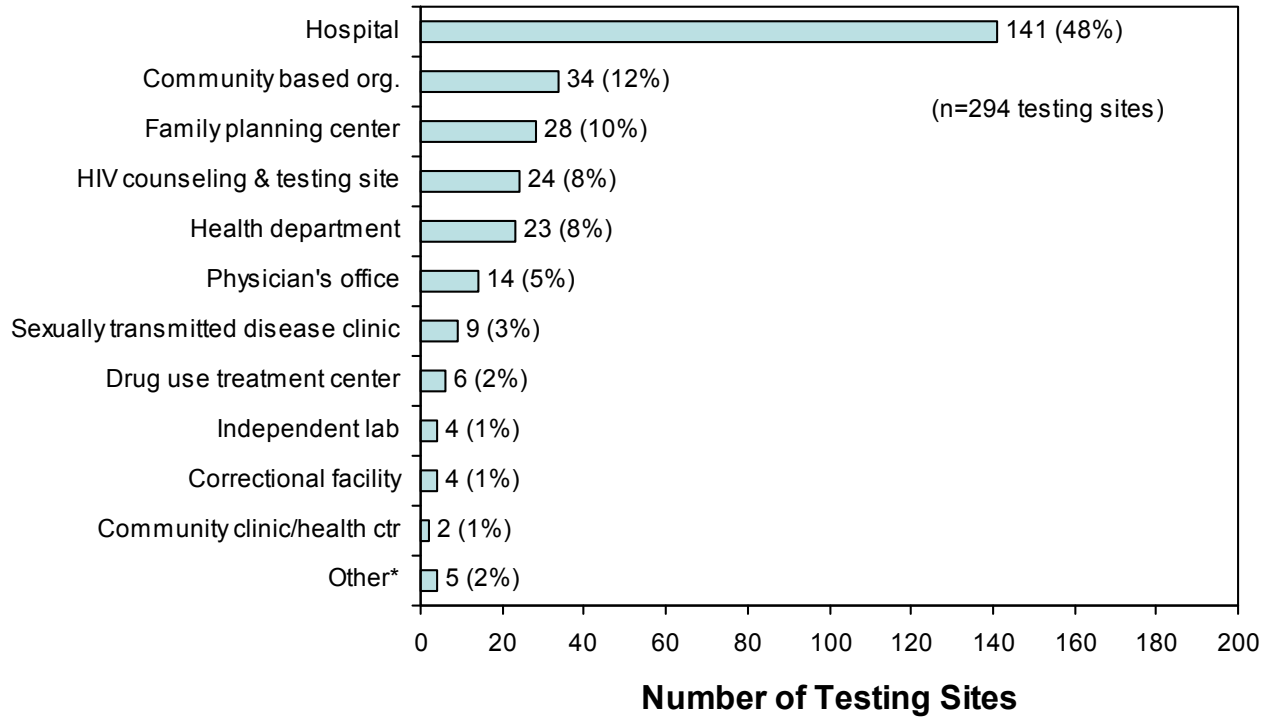
Note: Use of trade names is for identification only and does not imply endorsement by the Centers for Disease Control and Prevention

The following graphs and tables reference the number of facilities (n) and/or the number of responses (N) relative to each question.

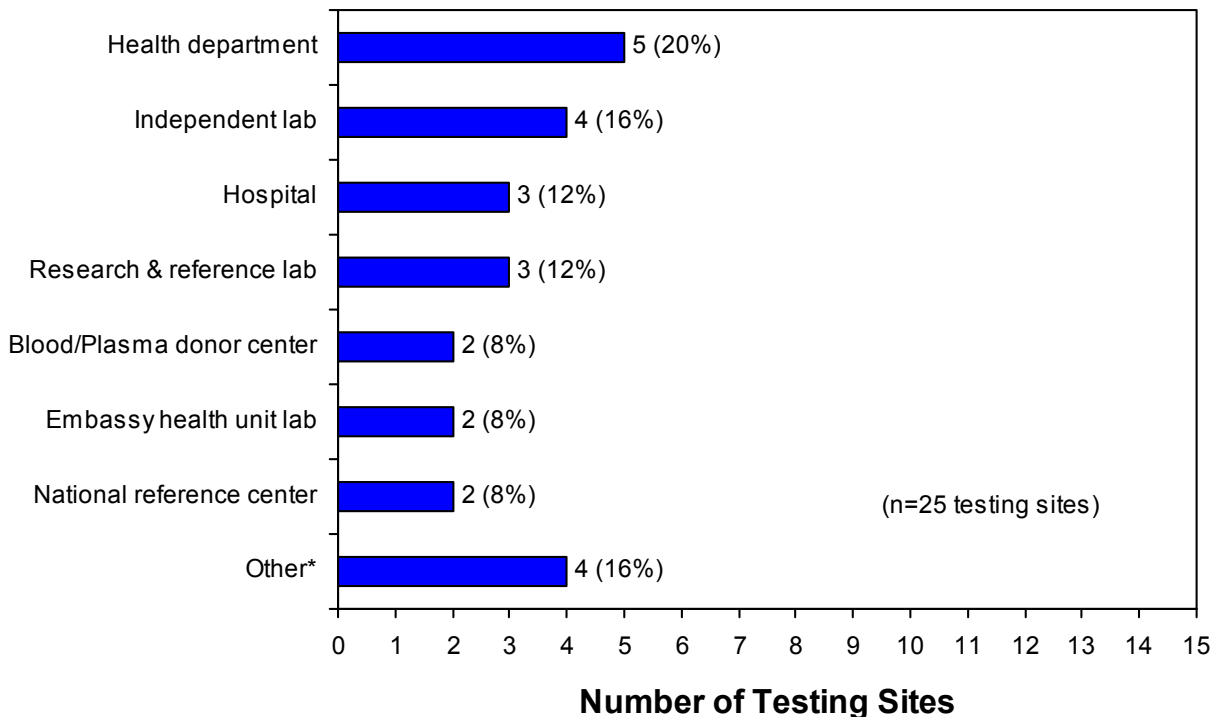
1.a) Please indicate the primary classification of your facility/testing site (Check one primary classification).

Note: 319/320 sites self-identified their facility in response to this question, as indicated in the following graphs. One U.S. site did not respond to the question.

Primary Type of U.S. Testing Site



Primary Type of Non-U.S. Testing Site



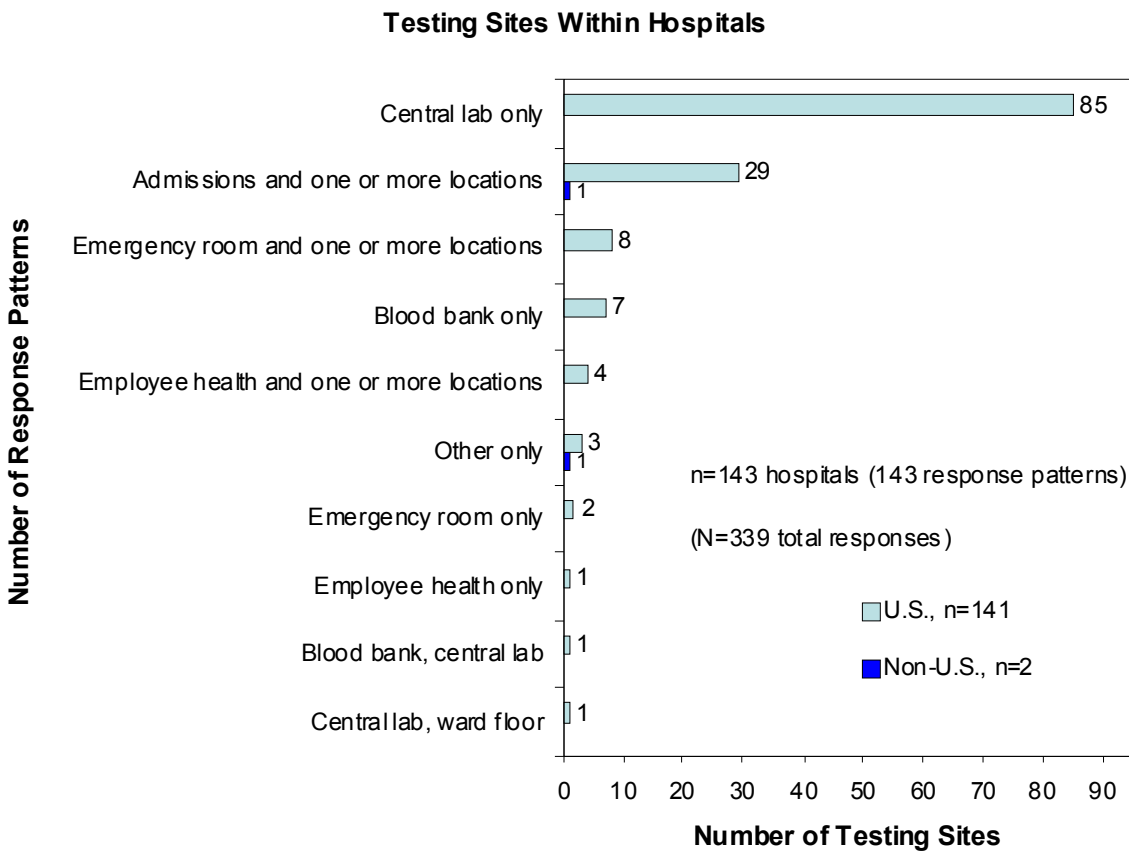
1.a) continued;

*The “Other” testing sites referred to in this questions included one each of the following:

- U.S. sites
 - health maintenance organization
 - clinic & field testing
 - Native American health clinic
 - health lab
 - university health center
- Non-U.S. sites
 - NGO (non-governmental organization)
 - HIV counseling & testing site
 - physician’s office
 - sexually transmitted disease clinic

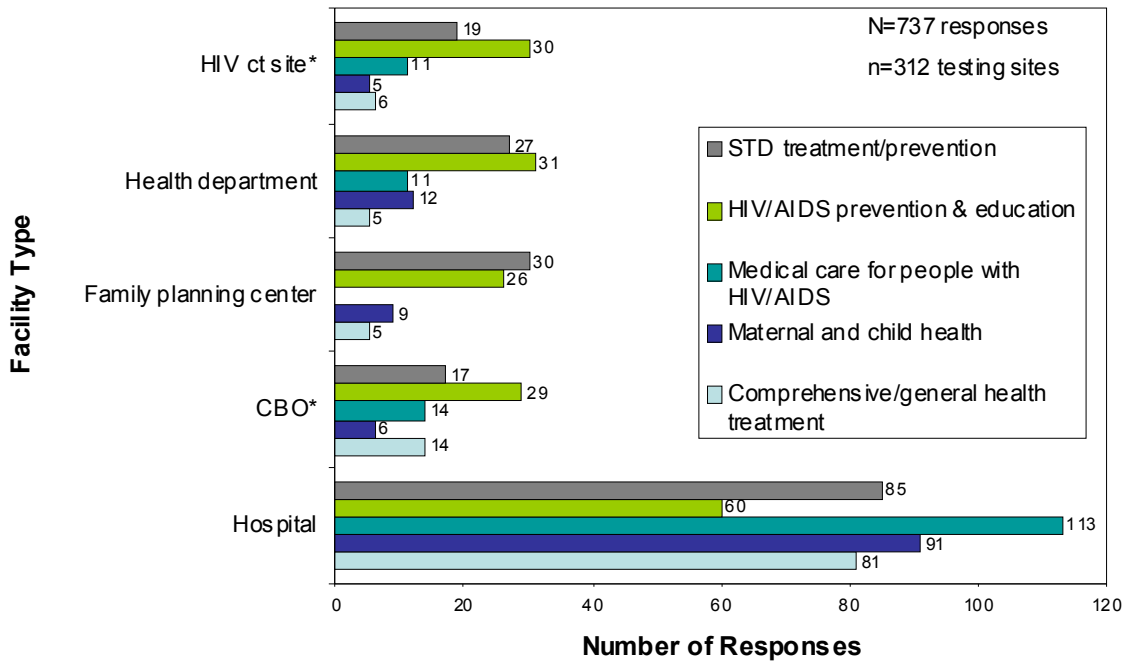
The following graph refers to those sites self-identifying as “Hospital” specifically to indicate all applicable sections/location within the hospital:

Note: The responses are grouped into the most commonly specified combinations of sections. One of the three non-U.S. hospital sites identified in question 1a did not specify a hospital section.



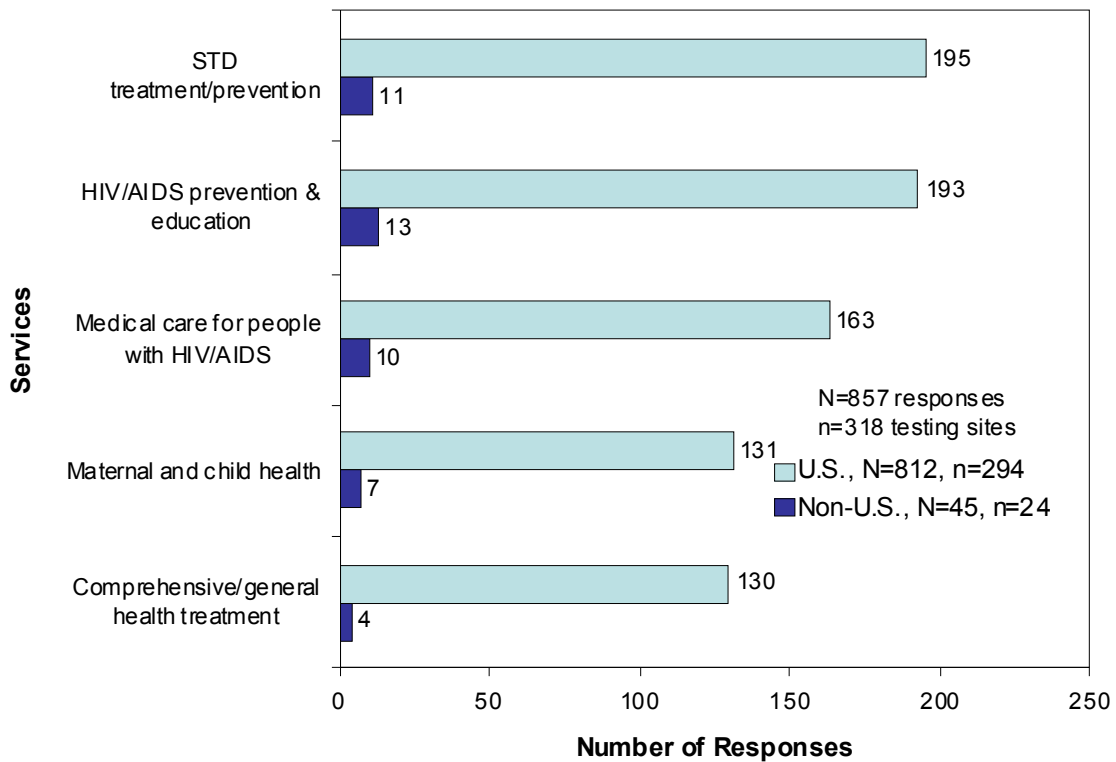
**1.b) Which of the following services does your organization provide?
(Check all that apply).**

Top 5 Services Provided by Top 5 U.S. and Non-U.S. Facility Types



* HIV ct site = HIV counseling and testing site
CBO = community based organization

Top 5 Services Provided by All U.S. and Non-U.S. Facilities



1.c) Does your facility currently perform HIV rapid testing?

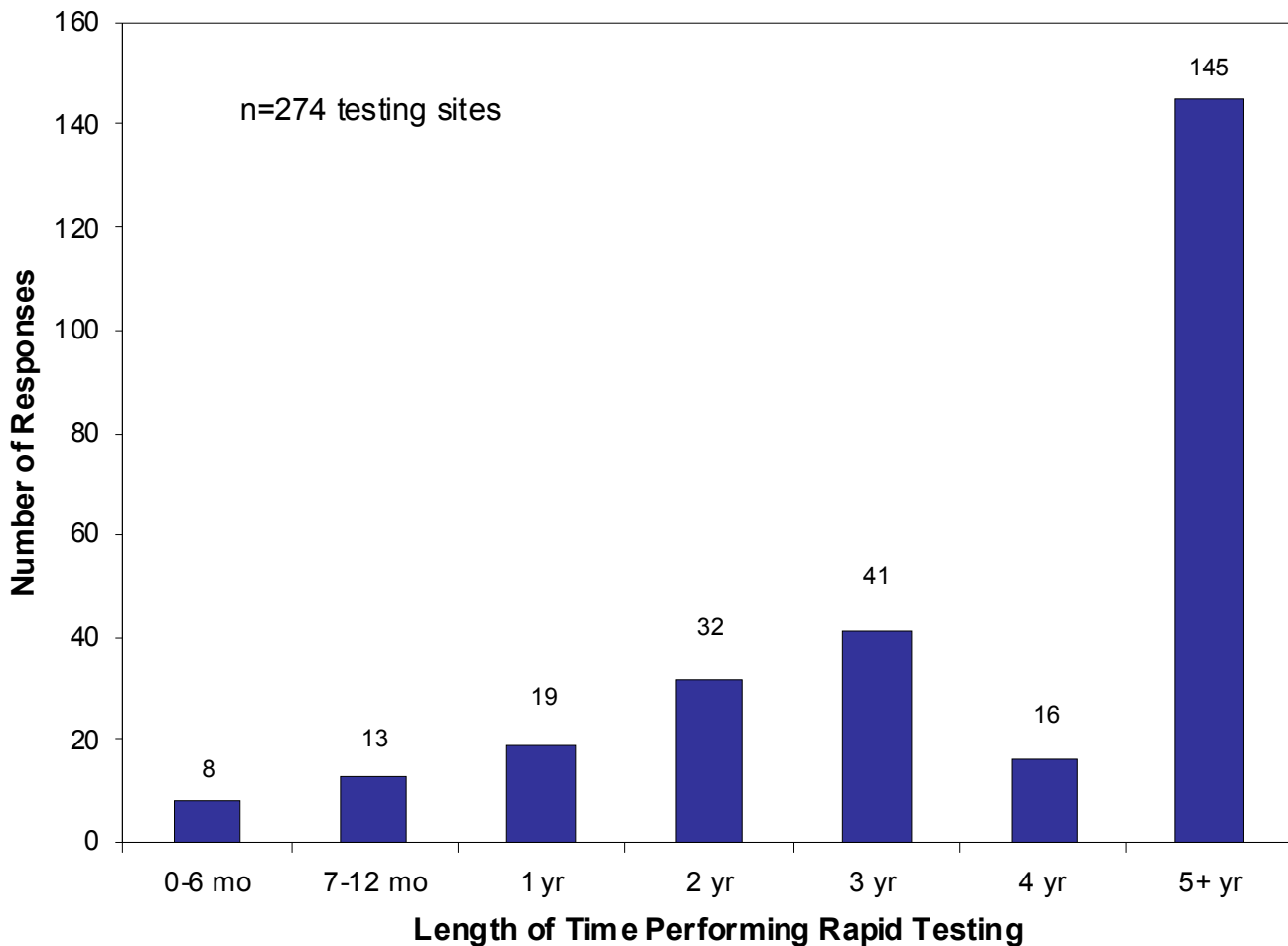
Response	Number of Facilities (%) (n=320)
Yes	298 (93.1%)
No*	22 (6.9%)

*These facilities were omitted from analyses regarding current testing practices

**1.d) If your facility does not perform HIV rapid testing, why not?
(Check all that apply).**

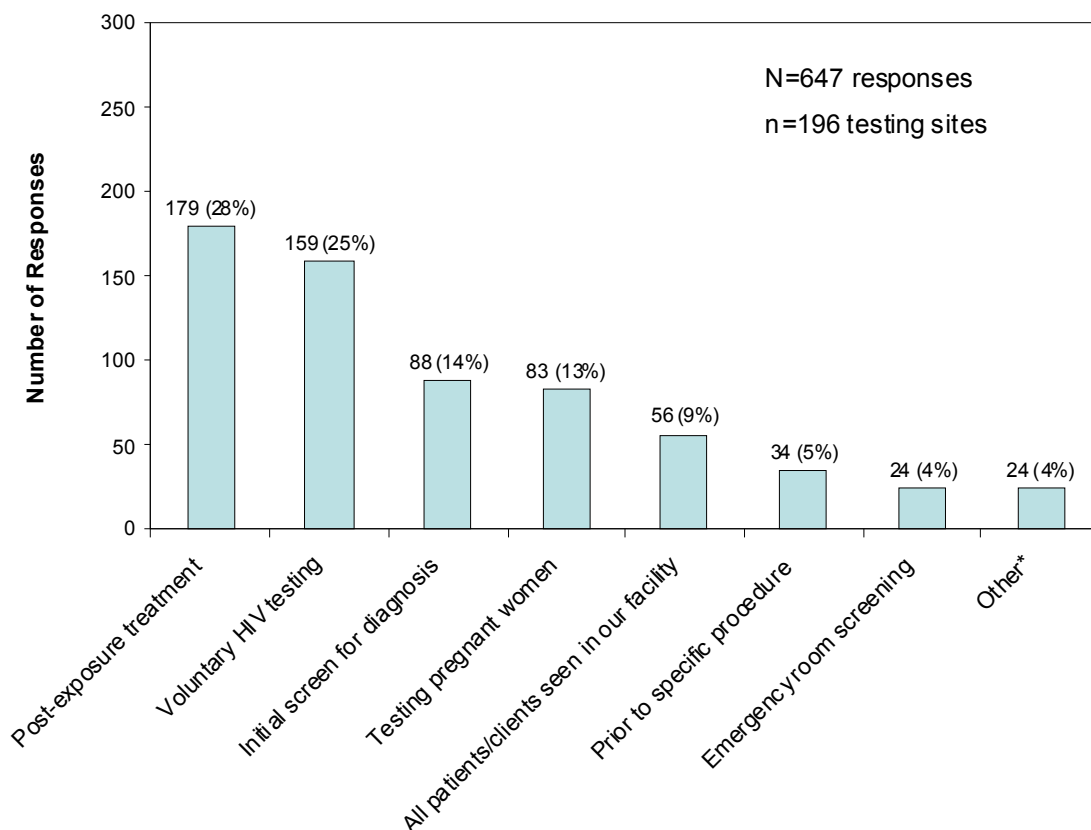
Of the 22 facilities that do not currently perform HIV rapid testing, 10 plan to start in the near future.

1.e) When did your facility begin to perform HIV rapid testing?



Note: 24 sites responded that the starting dates were unknown or provided no information about the starting date.

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



Of facilities indicating two purposes for testing, the top 3 combinations of answers for question 2a are shown in the table below:

Combination of responses	Number of response combinations
Testing pregnant women & post-exposure treatment	29
Initial screen for diagnosis & voluntary HIV testing	19
All patients/clients & voluntary HIV testing	15
Total	63

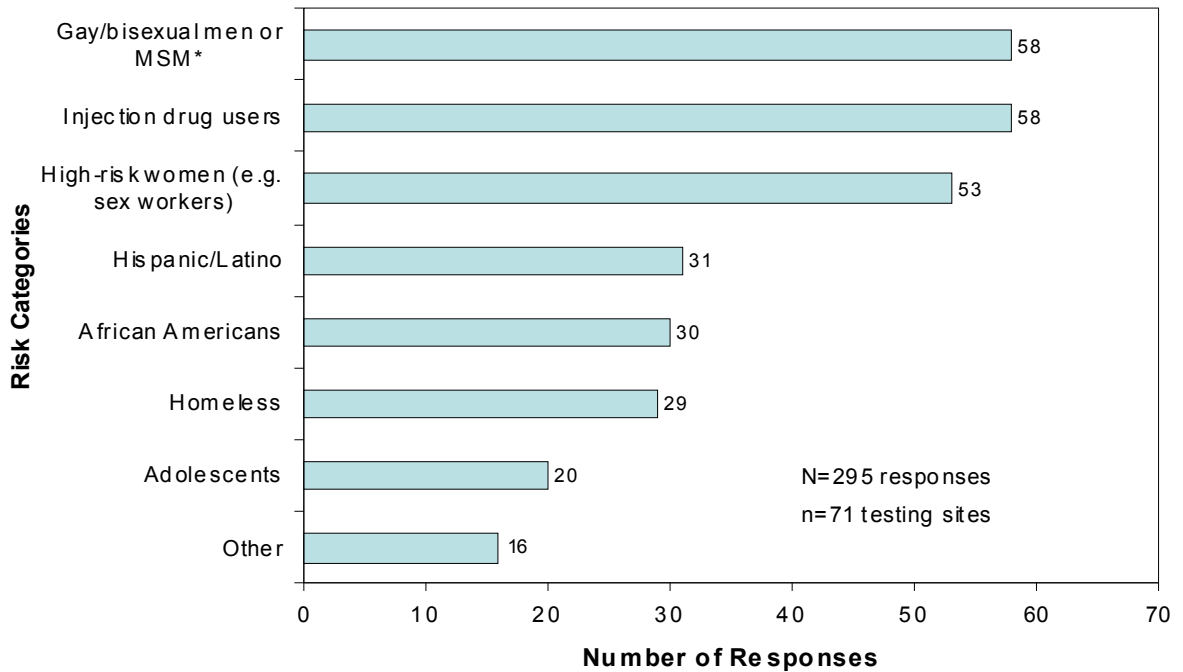
***Other HIV rapid testing purposes include:**

Purpose for Testing	Responses
Research/QA/manufacturing/clinical trials	6
As part of high-risk or STD exam	5
Blood donor/transplant (screening)	3
Premarital/visa/other license	3
Upon doctor's request	2
HIV-1 vs. HIV-2 differentiation	1
Patient/client is afraid of venipuncture	1
Mandatory for clients in harm-risk-reduction program	1
Patient incentive program	1
New employees	1

**2.b) What is the primary target population for your rapid testing program?
(Check only one).**

Primary target population	High risk group? (Y/N)	Number of testing sites
Any high risk client/patient	Y	47
Only certain types or categories of high risk clients	Y	33
Any client/patient requesting an HIV test	N	58
Any high school/college student	N	2
No specific target population	N	151

Of the 291 sites that answered the question, 80 reported a “high risk” group as their target population (see table above). 71/80 of these sites further defined their “high risk” group by selecting specific target high-risk categories (see graph below).

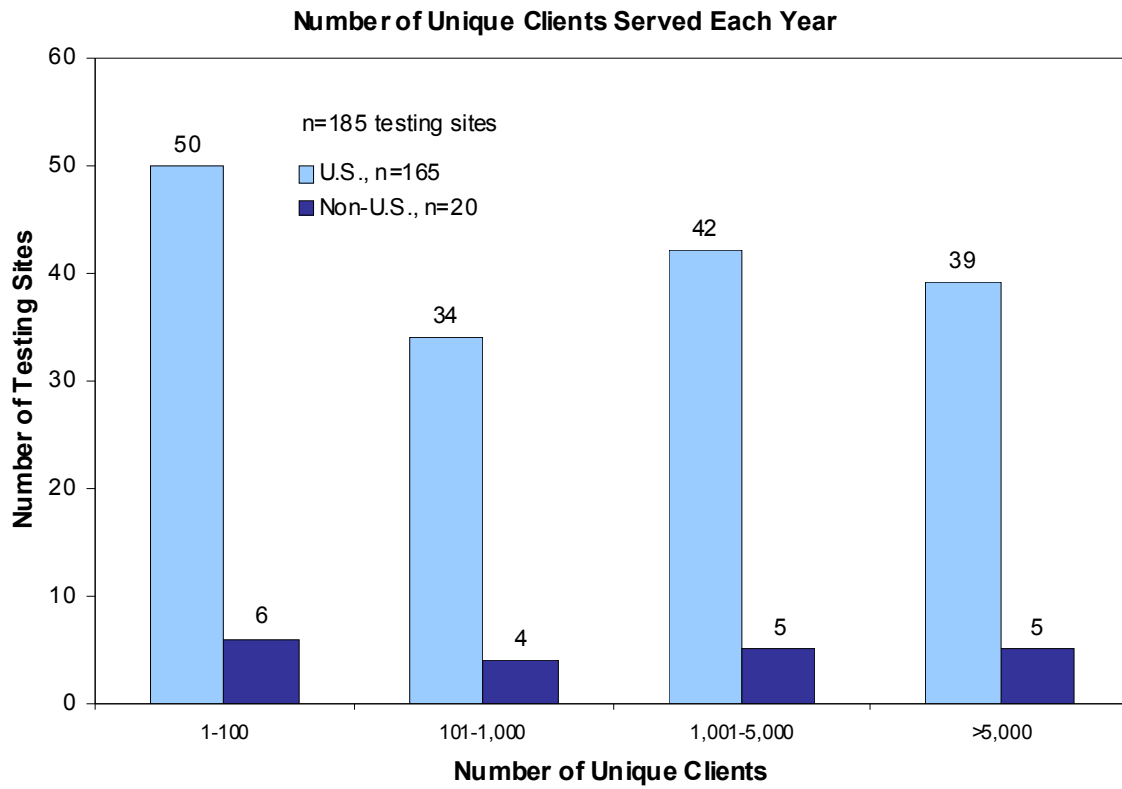


*MSM: men who have sex with men

The following describes the responses for “Other” in the above graph:

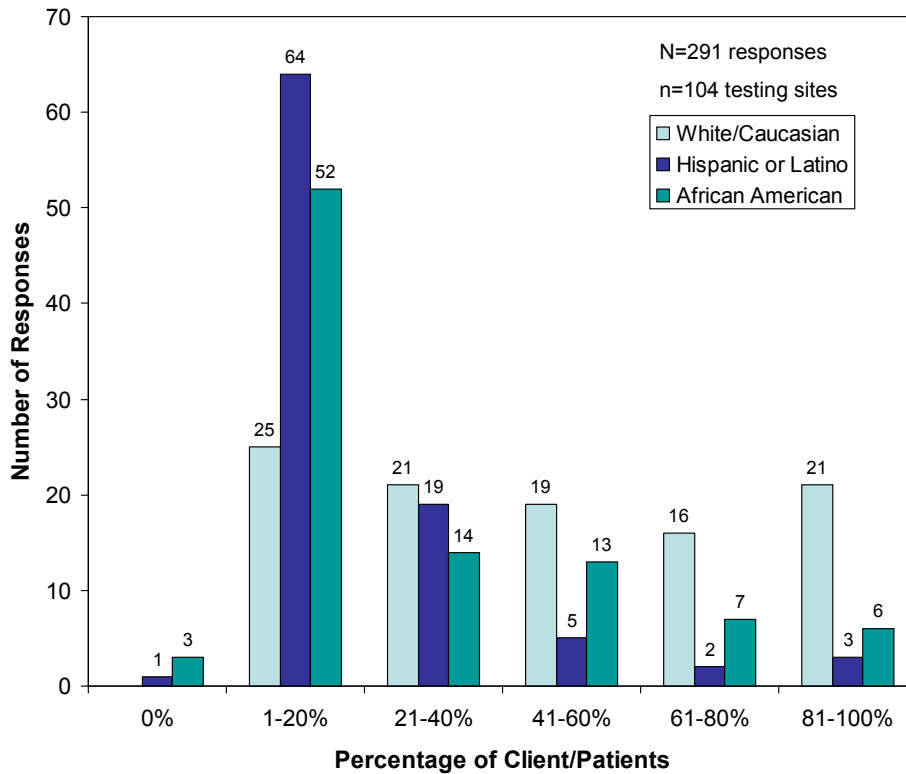
- partner of other high risk person (partner is HIV positive, MSM, sex worker, injection drug user, etc), N=6
- transgender community, N=4
- non-injection drug users, sexual assault survivor, or mentally ill, N=3
- inmate (adult or juvenile) N=2
- babies and/or children of HIV positive women, N=1

2.c) Approximately how many unique clients does your organization serve per year, across all programs, onsite and offsite?



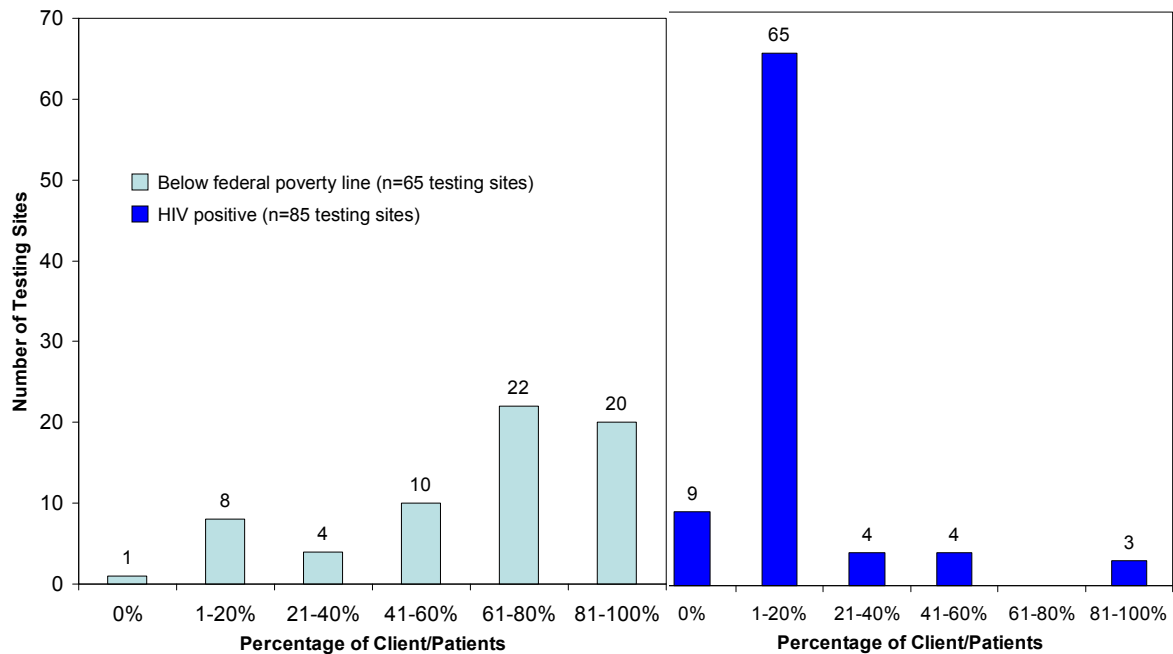
2.d) (U.S. sites only) Approximately what percentage of clients/patients seen in your organization have the ethnic backgrounds indicated?

Note: see third graph (on next page) for depiction of answer selections “Unknown”



Note: Some major ethnic groups were not included in the answer options for the above graph, including Pacific Islander, Asian and Native American.

(U.S. sites only) Approximately what percentage of client/patients seen in your organization: 1) are of HIV-positive status and 2) have incomes at or below the Federal poverty level?

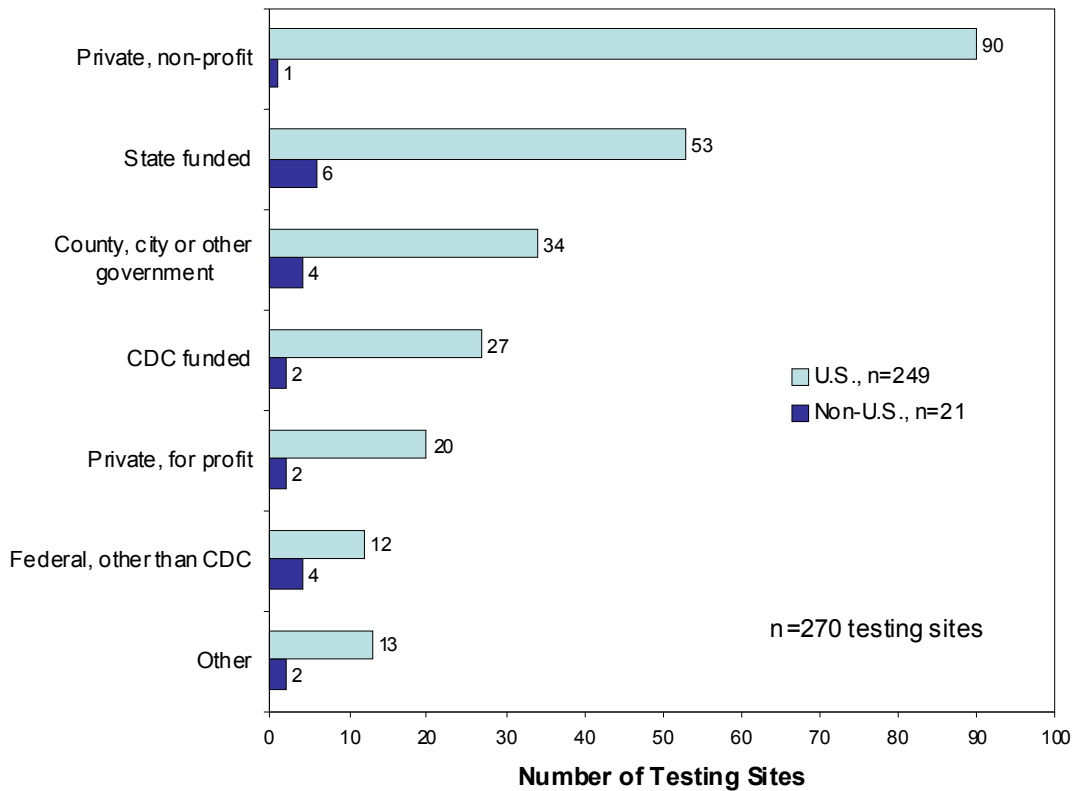


2.d) continued;

All of the 279 sites that answered question 2d regarding demographic data answered “unknown” to one or more of the demographic categories, therefore all responding sites were missing some or all of the demographic data.

- 134 sites answered “unknown” to one or more (but not all) of the options and
- 145 sites answered “unknown” to all of the options.

2.e) Who PRIMARILY funds your testing site? (Check only ONE BEST answer).



3.a) Of all HIV testing performed in your facility over the past year, what percentage was performed using HIV rapid test kits?

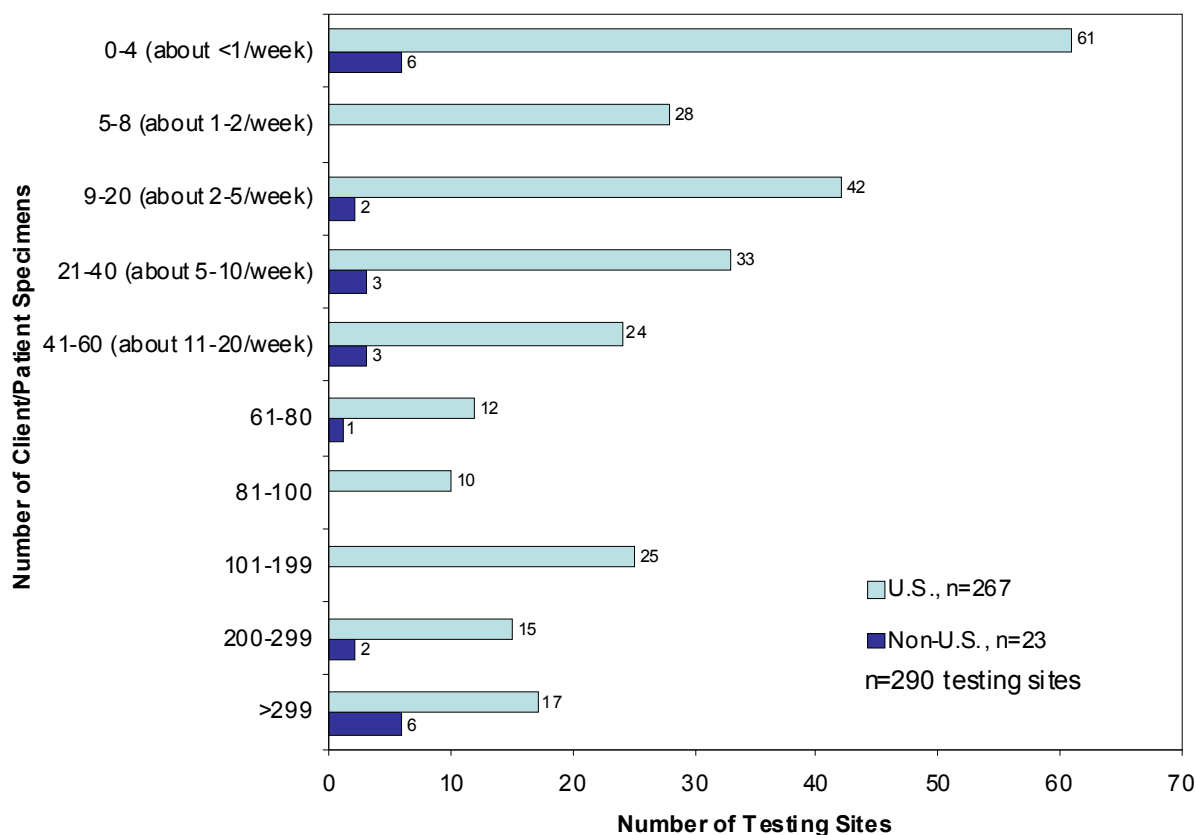
The table below breaks out the percent of HIV testing performed using HIV test kits by the type of facility.

Note: The percentages (rounded to the nearest whole number) are based on the number (n) of each facility type that answered the question.

Facility Type	Number of Sites	Percent of HIV testing performed using rapid HIV test kits, by facility type			
		≤10% rapid tests	11-74% rapid tests	75-99% rapid tests	100% rapid tests
Hospital	135	60 (44%)	14 (10%)	3 (2%)	58 (43%)
Health department	39	10 (26%)	12 (31%)	8 (21%)	9 (23%)
Independent	6	3 (50%)		2 (33%)	1 (17%)
Family planning center	9	1 (11%)	2 (22%)	4 (44%)	2 (22%)
Physician's office	8	2 (25%)		2 (25%)	4 (50%)
Community based org.	32		6 (19%)	10 (31%)	16 (50%)
Counseling & testing site	31	2 (6%)	4 (13%)	9 (29%)	16 (52%)
Other	10		3 (30%)	2 (20%)	5 (50%)
Alternative site*	13	1 (8%)	3 (23%)	3 (23%)	6 (46%)
Blood bank	9	5 (56%)	2 (22%)	1 (11%)	1 (11%)

*Alternative sites include: HMO, medical examiner, STD clinic, correctional facility, drug treatment center and mobile unit

3.b) How many client/patient specimens were tested using HIV rapid tests in your facility during the most recent representative MONTH?



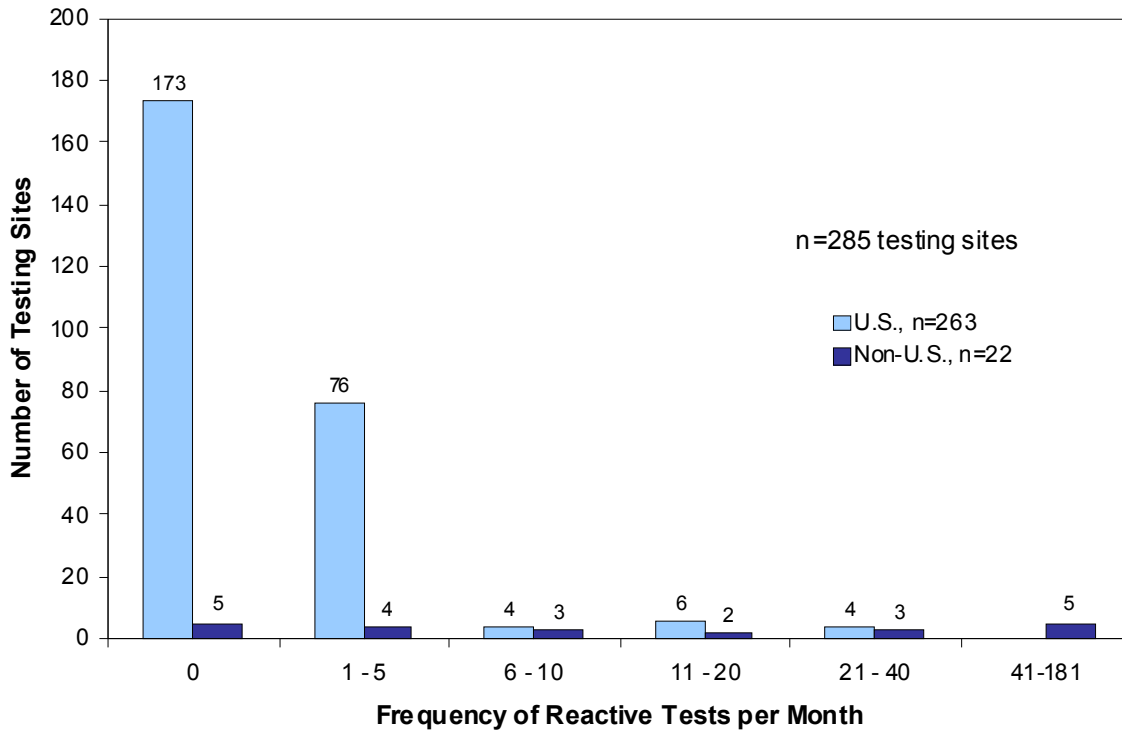
The table below shows the number of specimens tested in the most recent representative month broken out by type of facility.

Note: The percentages are based on the number (n) of each testing facility type that answered the question.

Facility Type	Number of Sites	Number of Specimens Tested in the Most Recent Month		
		≤30 HIV RT/representative month	31-99 HIV RT/representative month	≥100 HIV RT/representative month
Hospital	135	102 (76%)	19 (14%)	14 (10%)
Health department	38	13 (34%)	11 (29%)	14 (37%)
Independent	6	4 (67%)	1 (17%)	1 (17%)
Physician's office	8	4 (50%)	2 (25%)	2 (25%)
Community based org. (CBO)	31	14 (45%)	9 (29%)	8 (26%)
Other	10	5 (50%)	2 (20%)	3 (30%)
Family planning center	9	2 (22%)	3 (33%)	4 (44%)
Alternative site*	13	2 (15%)	6 (46%)	5 (38%)
Blood bank	9	5 (55%)	1 (11%)	3 (33%)
Counseling and testing center	31	10 (32%)	6 (19%)	15 (48%)

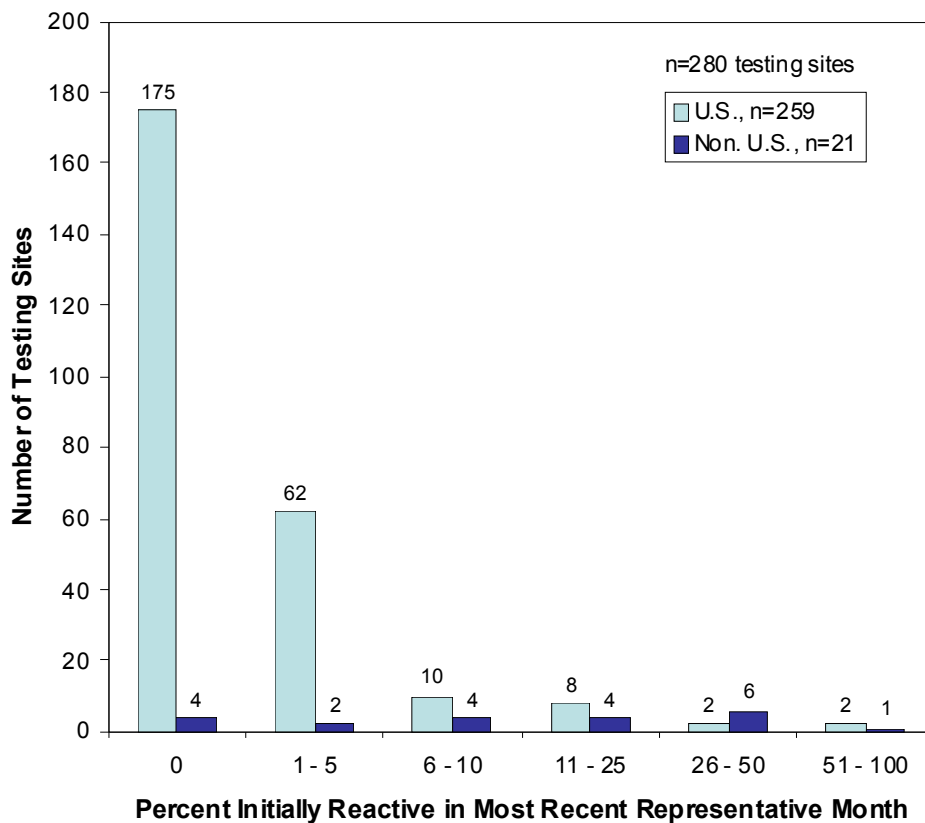
*Alternative sites include: HMO, medical examiner, STD clinic, correctional facility, drug treatment center and mobile unit

3.c) Of the specimens reported in question 3b above, how many were initially reactive (preliminary positive) during the same most recent representative MONTH?



The following graph depicts the calculated percentage of initially reactive HIV rapid tests performed in the most recent representative month.

Note: this graph is based on data from sites that also answered question 3b (the number of HIV rapid tests performed)



3.d) Of the above (see question 3c) initially reactive (preliminary positive) HIV rapid test results for which a confirmatory test was performed, how many were confirmed positive?

Note: the table below describes percentages based on the answers provided for question 3c.

Facility type	Percent confirmed positive				
	0-20	21-40	41-60	61-80	81-100
Hospital	3	1		1	20
Health department	1	1	2	1	18
HIV counseling and testing site			2	1	13
Community based organization	1	1	1		12
Alternative sites*			1		6
Other					2
Blood bank					1
Family planning center			1		
Total	5	3	7	3	72

*Alternative sites include: HMO, medical examiner, STD clinic, correctional facility, drug treatment center and mobile unit

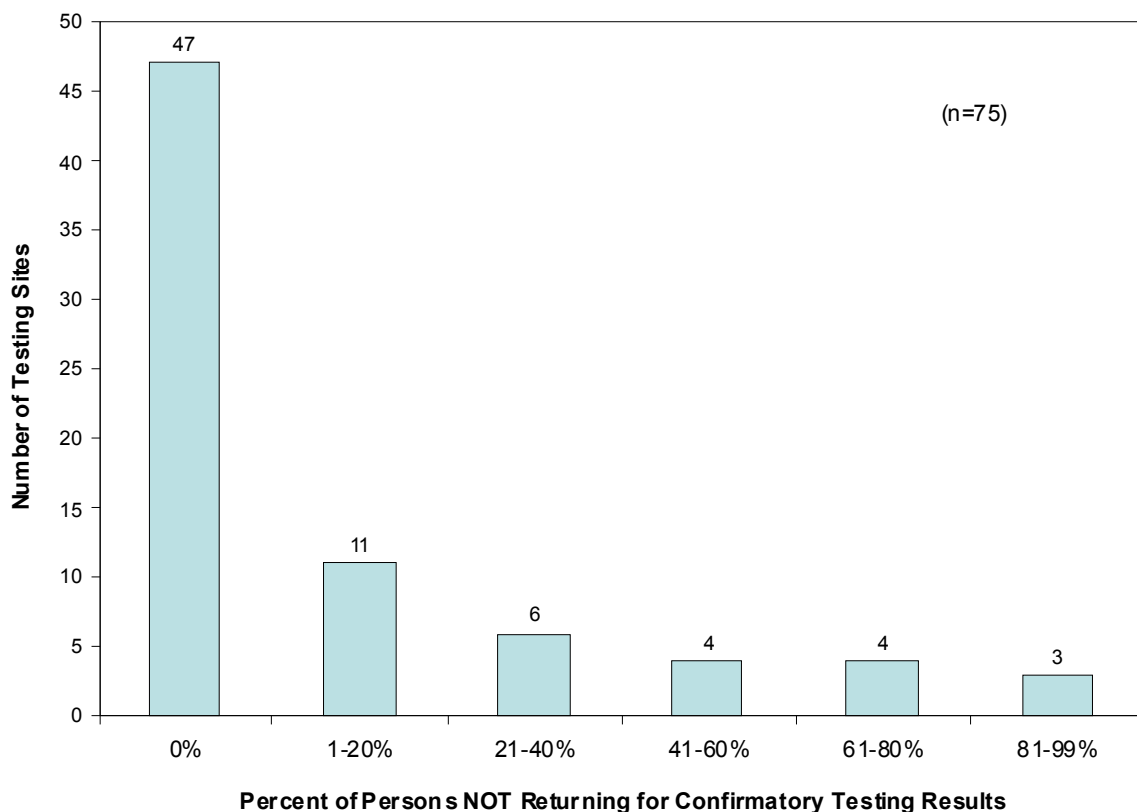
41 testing sites answered the question as follows: we have not had any reactive (preliminary positive) HIV rapid test results, n=34; we do not perform confirmatory testing, n=6; not applicable (N/A) - the client/patient is referred elsewhere for confirmatory testing (the results are unknown), n=1.

Over half of the reporting testing sites currently performing HIV rapid testing, (167/298; 56%) did not answer the above question; this may be due to lack of information or understanding regarding confirmatory test results.

3.e) In the last 6 months, how many persons received preliminary positive results, but did not return for confirmatory test results?

The following graph gives the percent of U.S. clients/patients who did NOT return for their confirmatory test results.

Note: this graph is based on data from those U.S. sites who answered both parts of question 3e, i.e. sites that gave data for the number of persons with initially reactive HIV rapid testing results and also gave data for the total number of persons not returning for confirmatory results.



There were 11 U.S. sites that reported 100% of their clients/patients did not return for confirmatory test results in the last six months; these sites are listed by type of facility in the table below.

Facility type	100% of persons NOT returning for confirmatory results
Hospital	4
Community based organization	3
Health department	2
Alternative sites*	2

*Alternative sites include: HMO, medical examiner, STD clinic, correctional facility, drug treatment center and mobile unit

The following describes the other selections by 30 U.S. sites:

- we do not require confirmatory testing, n=1
- persons are sent elsewhere for confirmatory testing and we do not receive those results, n=9
- no information available to us on confirmatory testing, n=20

3.f) If HIV screening tests other than rapid tests are offered in your facility, what percentage of patients/clients in the last 6 months with preliminary positive results [from these other tests] did not return for confirmatory results?

Note: Not all testing sites offer HIV screening tests other than the HIV rapid test method.

Of the 240 sites that answered the question, 95/240 (40%) U.S. and non-U.S. testing sites had information regarding their clients/patients returning for confirmatory testing results.

The responses given by U.S. sites (n=87), by type of facility, is shown in the table below.

Facility Type	Percent not returning for confirmatory testing		
	0	1-24	50-69
Blood bank	4		
Hospital	32	2	2
Health department	10	2	
Independent	2		
Family planning center	4		
Alternative sites*	4		
Physician's office	1		
Counseling and testing site	11	2	
Community based organization	10	1	
Other			
Total	78	7	2

The responses given by eight non-US sites were as follows:

- 7/8 indicated 0% clients/patients not returning for confirmatory testing results, and
- 1/8 indicated 1% clients/patients not returning for confirmatory testing results.

“Other responses” given by all sites (n=145) are shown below:

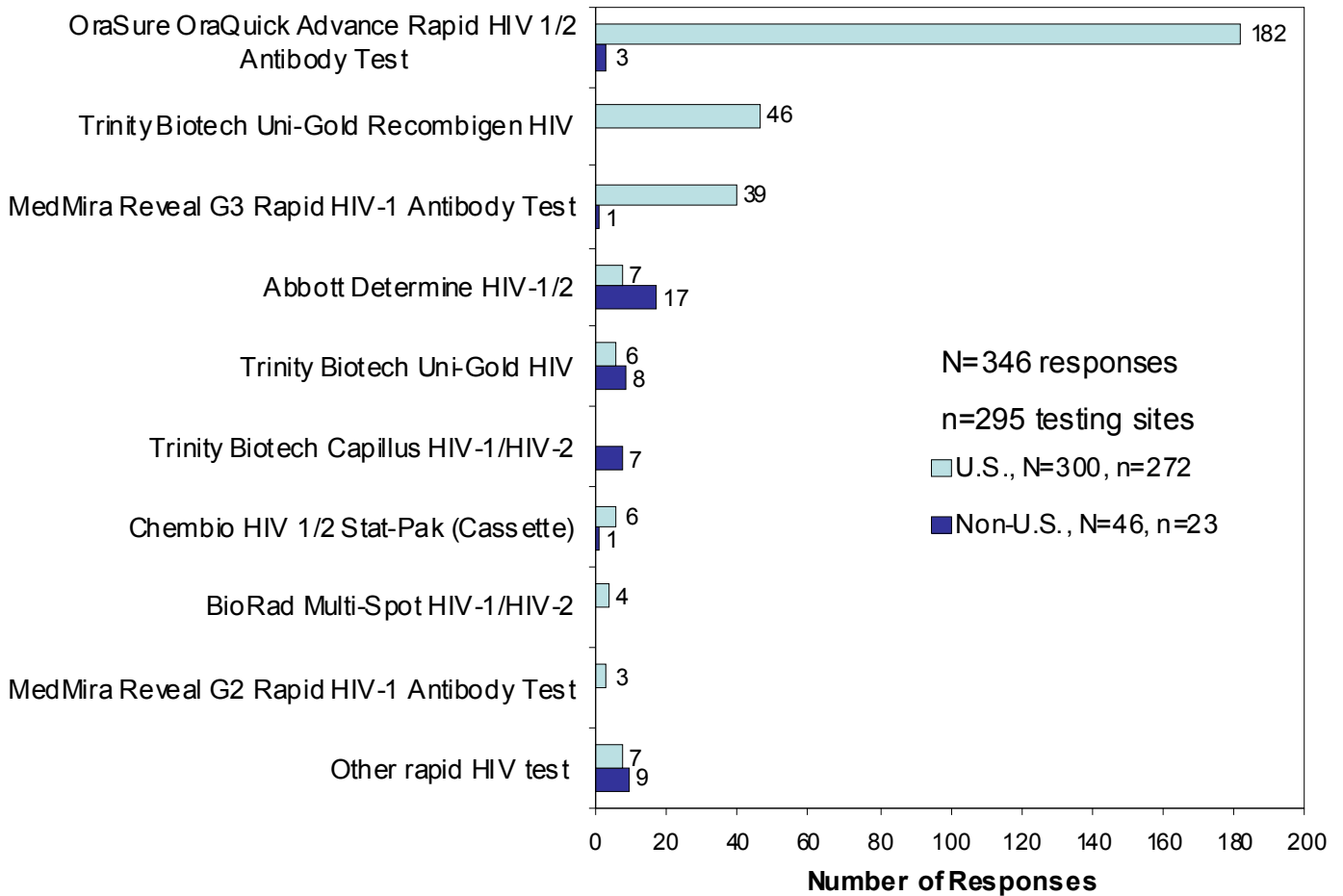
- N/A, other HIV tests are not performed in our facility, n=99 (96 U.S., 3 non-U.S. sites)
- N/A, confirmatory testing is not required for other (not rapid) HIV screening test(s), n=14 (3 U.S., 11 non-U.S. sites)
- N/A, persons sent elsewhere for confirmatory testing and we do not receive test results, n=3 (all U.S. sites)
- Don't know; no information available on confirmatory testing for our other (not rapid) HIV screening test(s), n=29 (27 U.S., 2 non-U.S. sites)

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

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

Less than half (120/289, 42%) of the testing sites answering the question responded that they provide anonymous testing, while nearly 100% (286/289, 99%) protect the confidentiality of the client/patient being tested for HIV.

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



The following tables outline the “Other” responses to the above question:

U.S. Sites

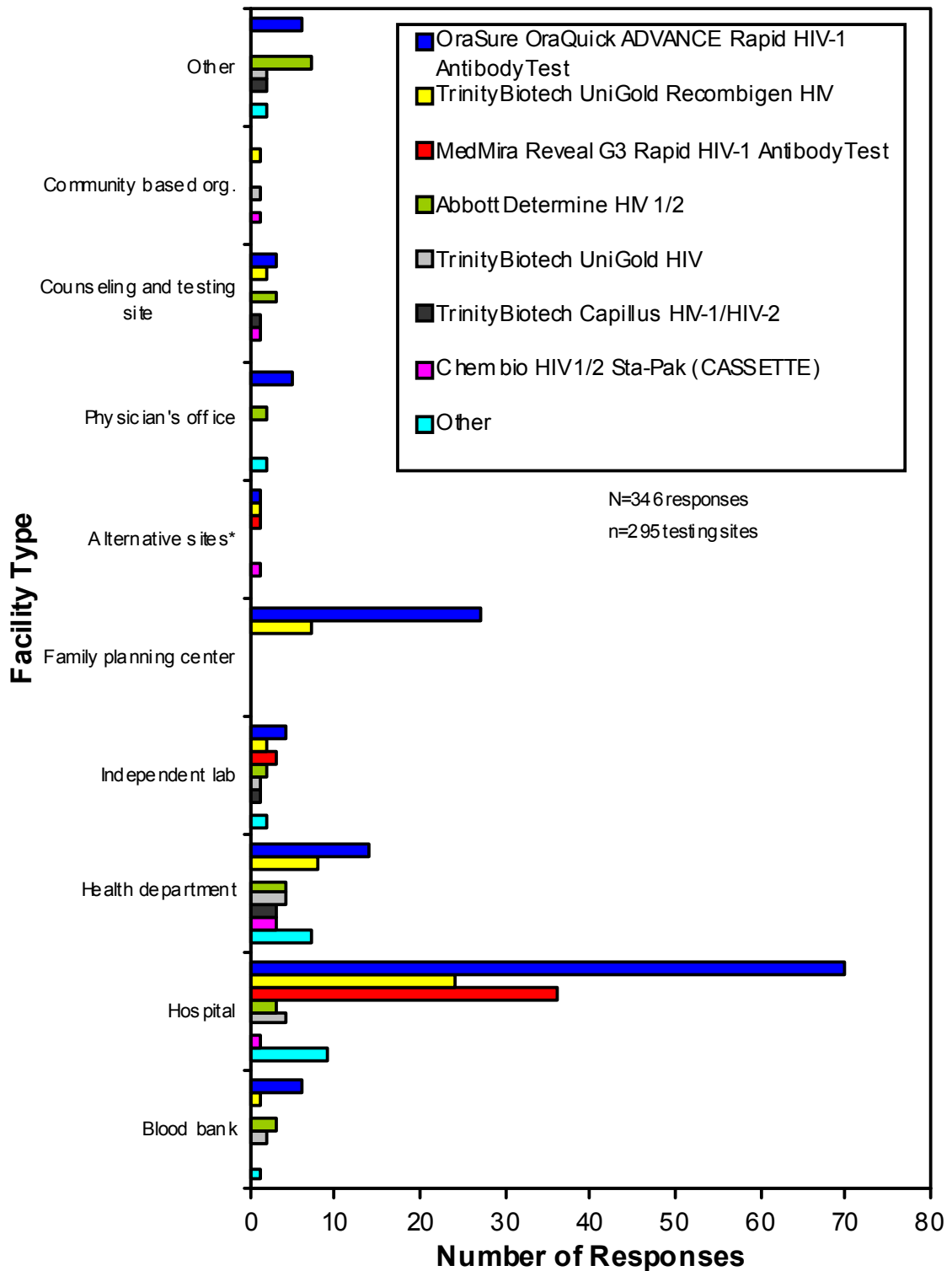
Other kit responses indicated	Total
Clearview HIV 1/2 Stat-Pak by Inverness Medical	5
Not Specified	2

Non-U.S. Sites

Other kit responses indicated	Total
Immunocomb by PBS Orgenics Hexagon by Human	1
SD BioLine HIV	1
Not specified	7

5.) *continued;*

The graph below shows the type of test kit used by different types of facilities:



* Alternative sites include: HMO, medical examiner, STD clinic, correctional facility, drug treatment center and mobile unit

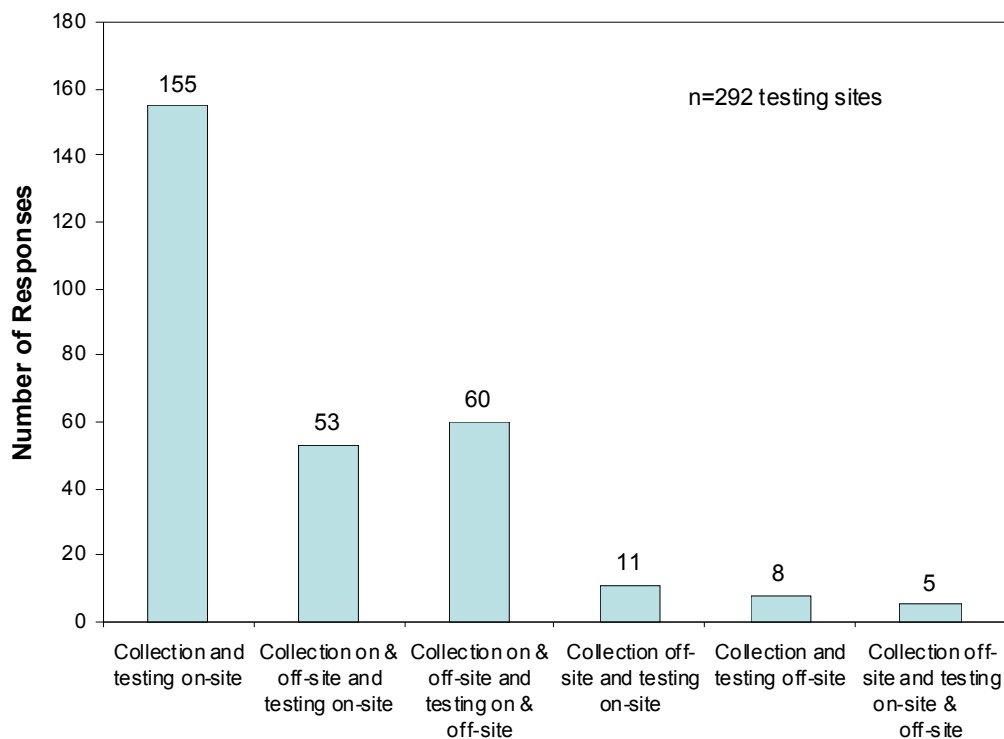
6.) What sample type(s) do you currently use for HIV rapid testing? (Check all that apply).

Note: “Serum” and “plasma” responses reflect both fresh and frozen specimens.

Sample combinations of responses	Number of sites (n=294)
Serum	49
Serum, Plasma	40
Whole blood (venous)	38
Whole blood (fingerstick)	31
Oral Fluid	24
Whole blood (fingerstick), Whole blood (venous)	21
Whole blood (fingerstick), Oral Fluid	20
Whole blood (fingerstick), Whole blood (venous), Oral Fluid	20
Plasma	14
Serum, Plasma, Whole blood (fingerstick), Whole blood (venous)	10
Plasma, Whole blood (venous)	6
Serum, Plasma, Whole blood (fingerstick)	3
Serum, Plasma, Whole blood (venous)	3
Whole blood (venous), Oral Fluid	3
Serum, Whole blood (fingerstick)	2
Serum, Whole blood (venous)	2
Serum, Whole blood (fingerstick), Whole blood (venous)	2
Plasma, Whole blood (fingerstick)	1
Plasma, Whole blood (fingerstick), Whole blood (venous),,	1
Serum, Oral Fluid	1
Serum, Plasma, Oral Fluid	1
Serum, Plasma, Whole blood (fingerstick), Oral Fluid	1
Serum, Plasma, Whole blood (venous), Oral Fluid	1

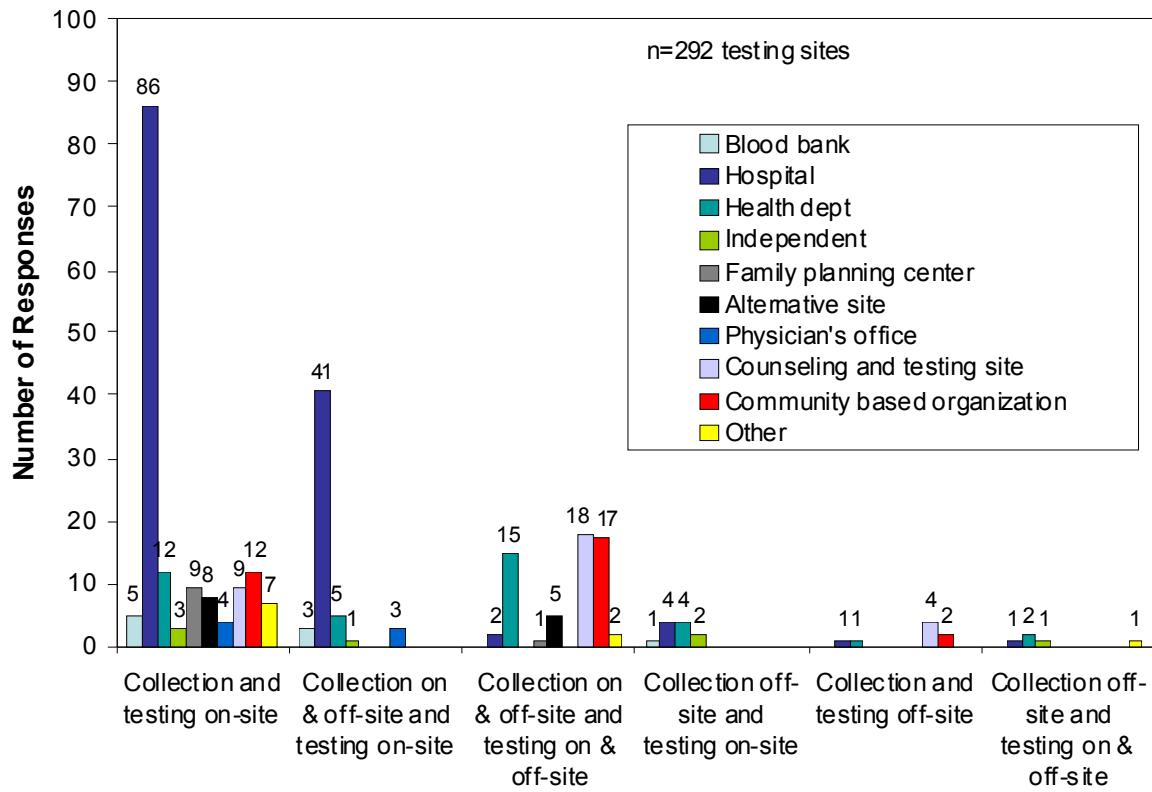
7.a) Where are specimens collected and HIV rapid testing performed?

Please note: ON-SITE=within your facility; OFF-SITE=outside your facility



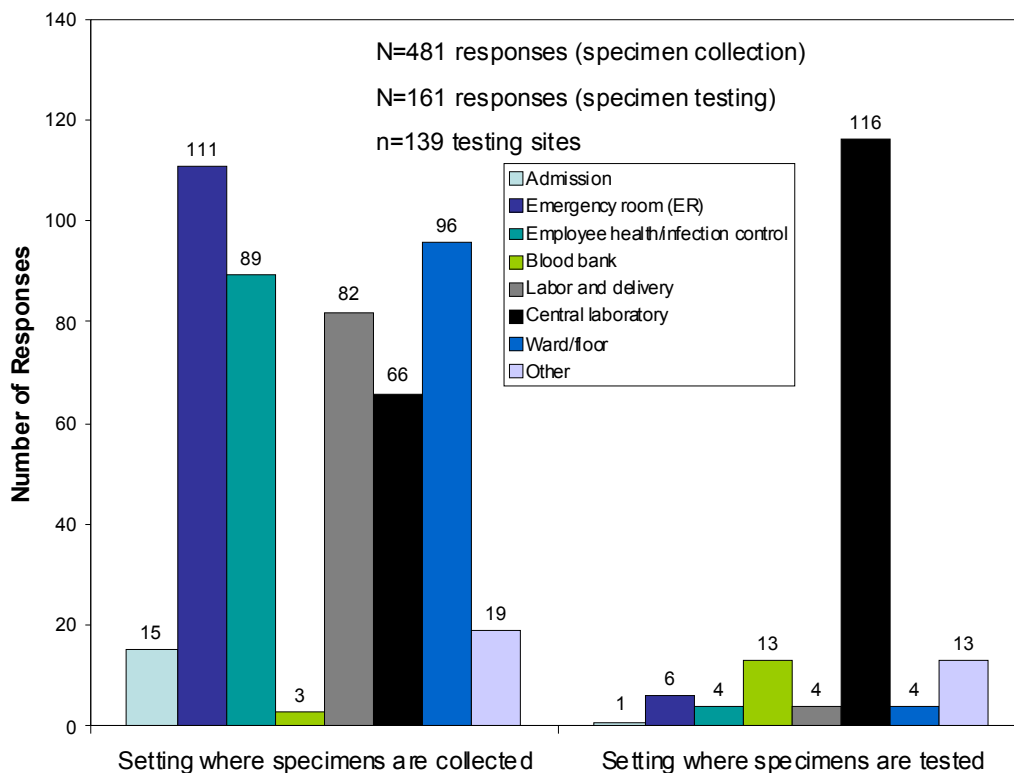
7.a) continued;

The following graph shows the location of specimen collection by type of facility.



7.b) For Hospitals only: In what hospital setting are specimens collected?
(Check all that apply).

7.c) For Hospitals only: In what hospital setting are specimens tested?
(Check all that apply).



“Other” collection in a hospital setting

Hospital Area	Responses
OR and/or surgery floor	4
Clinics and other hospital units	4
Site of employee exposure to potentially infectious material	3
Outpatient draw area	2
Other hospital lab	2
Nursing unit/nursing home care	2
All hospital units	1
Neonatal ICU	1

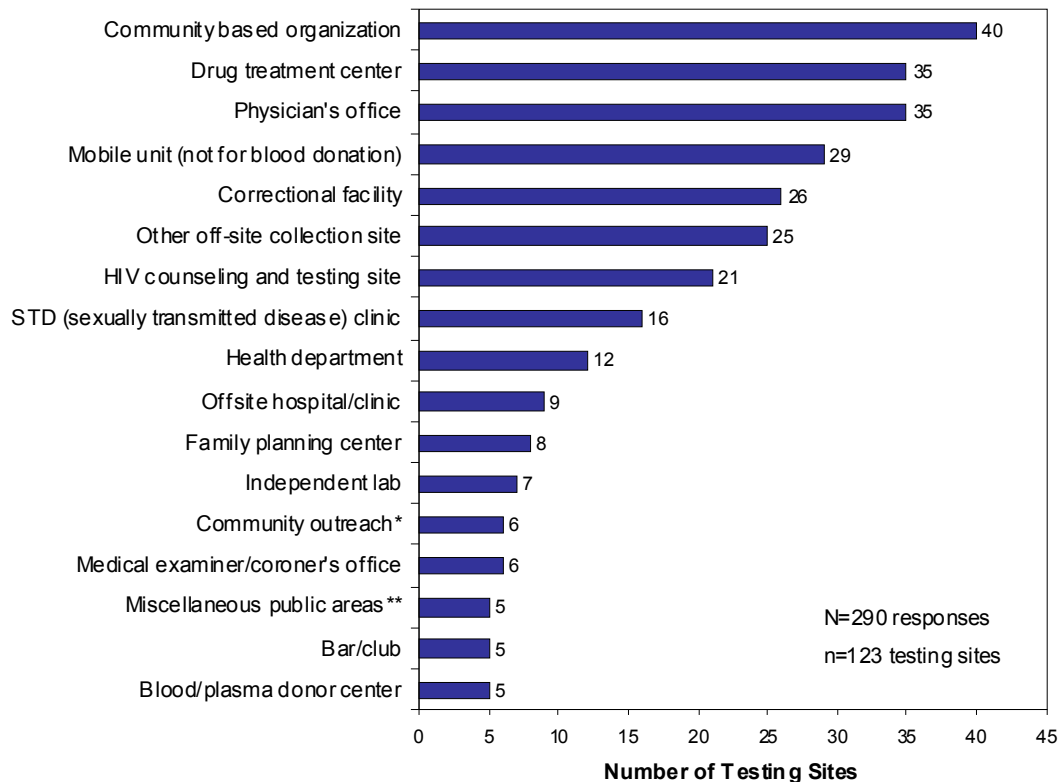
“Other” testing in a hospital setting

Hospital Area	Responses
Other hospital lab	9
Clinic	1
Private testing area	1
Centralized Transfusion Service area (CTS)	1
Not specified	1

7.d) Question 7d is ONLY for sites that collect specimens off-site for HIV rapid testing. If you perform HIV rapid testing on specimens collected off-site (outside your facility), please indicate where these specimens are collected. (Check all that apply).

The following graph depicts the specific off-site testing locations.

Note: more than one location could be selected.



* Community outreach includes: shelter, rescue mission, halfway-recovery house, community center, food-soup kitchen.

** Miscellaneous public areas include: stores, street, needle exchange program, mental health facility, juvenile detention center, draw stations, retreats.

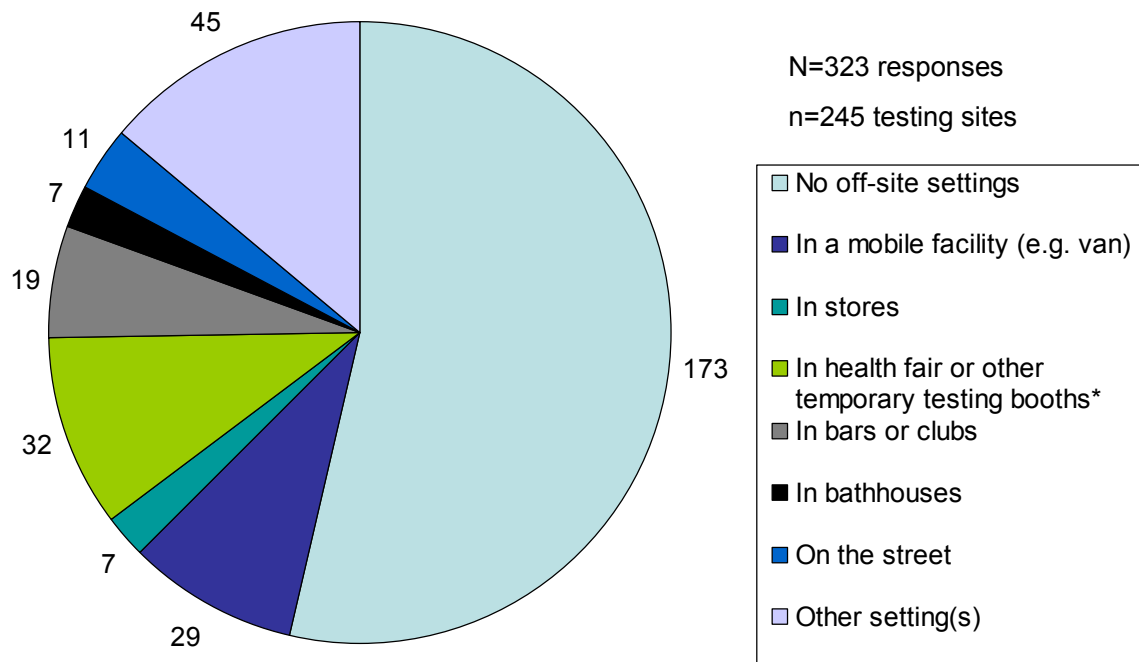
The table below outlines the responses for “Other” in the above graph:

Category	Responses
Employee health, occupational medicine, or other occupational exposure area	4
Nursing home/center, extended stay	3
Military (other than hospital)	3
Health fair, "booth", or other public functions/events	2
Church or school	1
Health maintenance organization (HMO)	1
Misc. multiple combinations of off-site collection locations	11

7.e) In which off-site settings does your organization perform rapid HIV tests?

The following table depicts the specific off-site testing locations.

Note: More than one location could be selected and 173 responses indicated “no off-site settings”.



*Health fair or other temporary testing booth

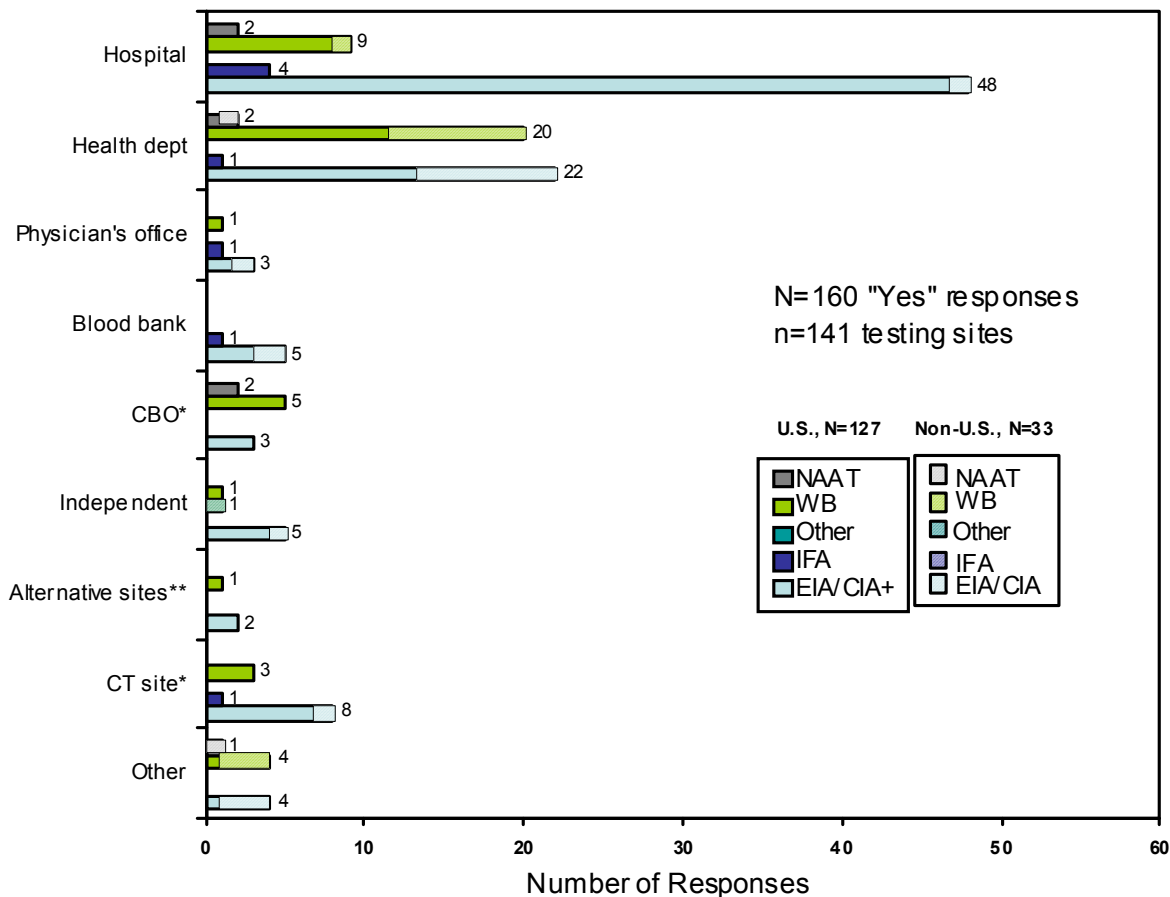
The table below outlines the responses for “Other” in the above question:

Category	Responses
Correctional facility	6
Community centers, CBO sites	6
Other off-site (home, office, race track, retreats, "field followup", counseling service)	5
Drug treatment center/needle exchange program site	4
Church or school	3
Health department/clinic	3
Sexually transmitted disease (STD) clinic	1
Shelters/temp housing (e.g. homeless, halfway house)	1
Unknown/not specified	1
Misc. multiple combinations of off-site collection locations	15

8.) To detect HIV infection, do you currently perform a test in your facility other than an HIV rapid test?

The following graph represents “Yes” responses to the question; please note that sites could select more than one type of non-rapid HIV test.

Note: The one “Other” test kit type in the graph was specified as a “line immunoassay” by a non-U.S. site listed as an “Independent” facility type.



*CBO = Community based organization
CT Site = Counseling and testing site

** Alternative sites include: HMO, medical examiner, STD clinic, correctional facility, drug treatment center and mobile unit

+ EIA = enzyme-linked immunoassay
CIA= Chemiluminescence assay
NAAT = Nucleic acid amplification test

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

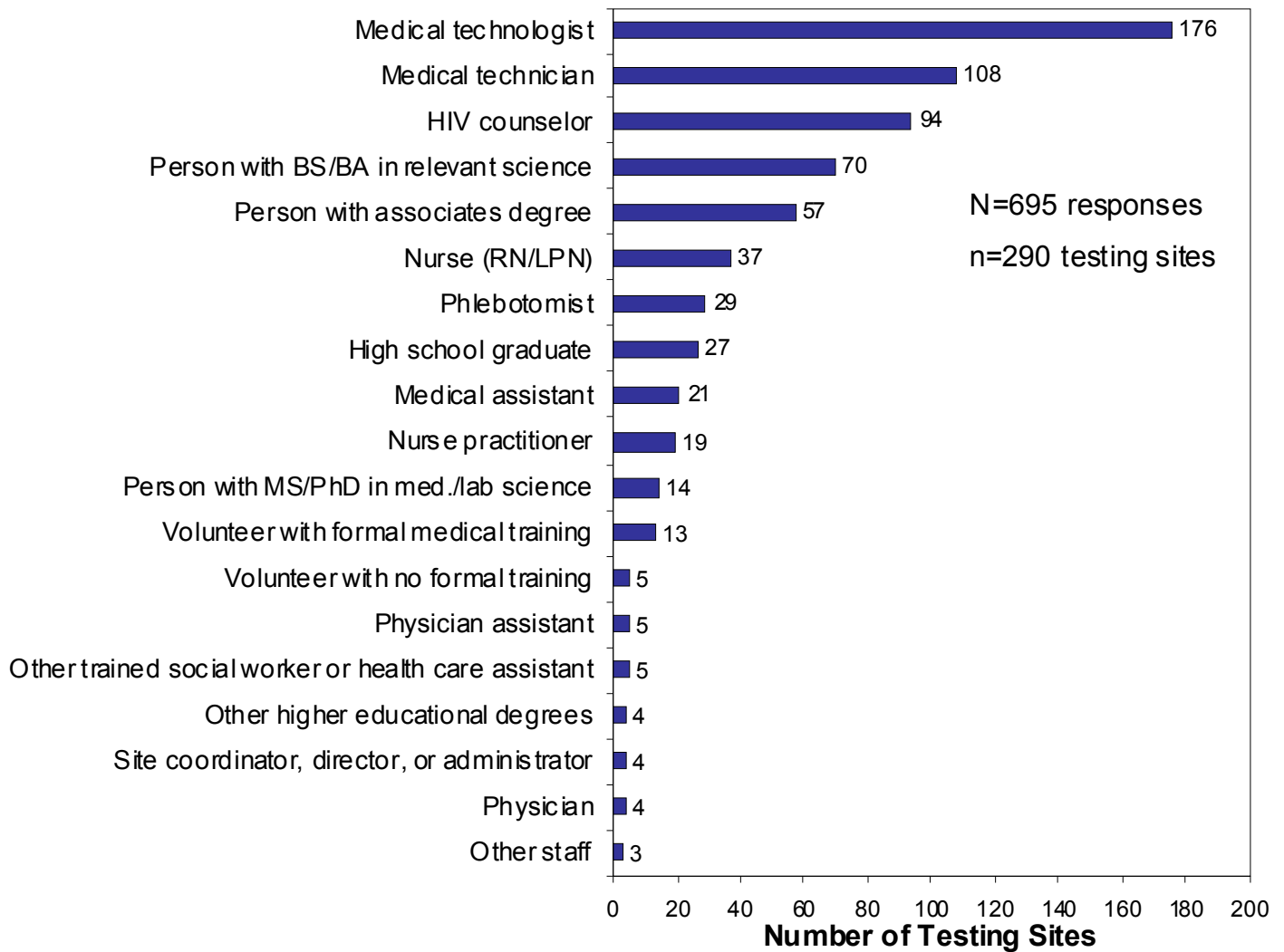
Please note: This does not refer to changing to another HIV rapid test method.

In answer to the question, 86% said they did not replace and 13% said they did replace another method of HIV testing with HIV rapid testing. Of those who said “Yes”, the following table specifies their responses.

Note: sites could select more than one HIV test, e.g. HIV rapid testing might have replaced both EIA and Western blot HIV tests.

Specified "Yes" responses	Responses
EIA	
OraSure EIA	6
Abbott (not specified)	5
Biorad Genetic Systems	4
Unknown	2
Not specified	2
BioMerieux Vironostika	1
Genscreen HIV-1/2 v.2	1
Sanofi	1
SUDS	1
Syra	1
Other	
OraSure oral fluid	6
Oral fluid test (not specified)	2
Not specified	1
Western blot	
OraSure western blot	2
Bioline	1
HIV Blot 2.2	1
Not specified	1

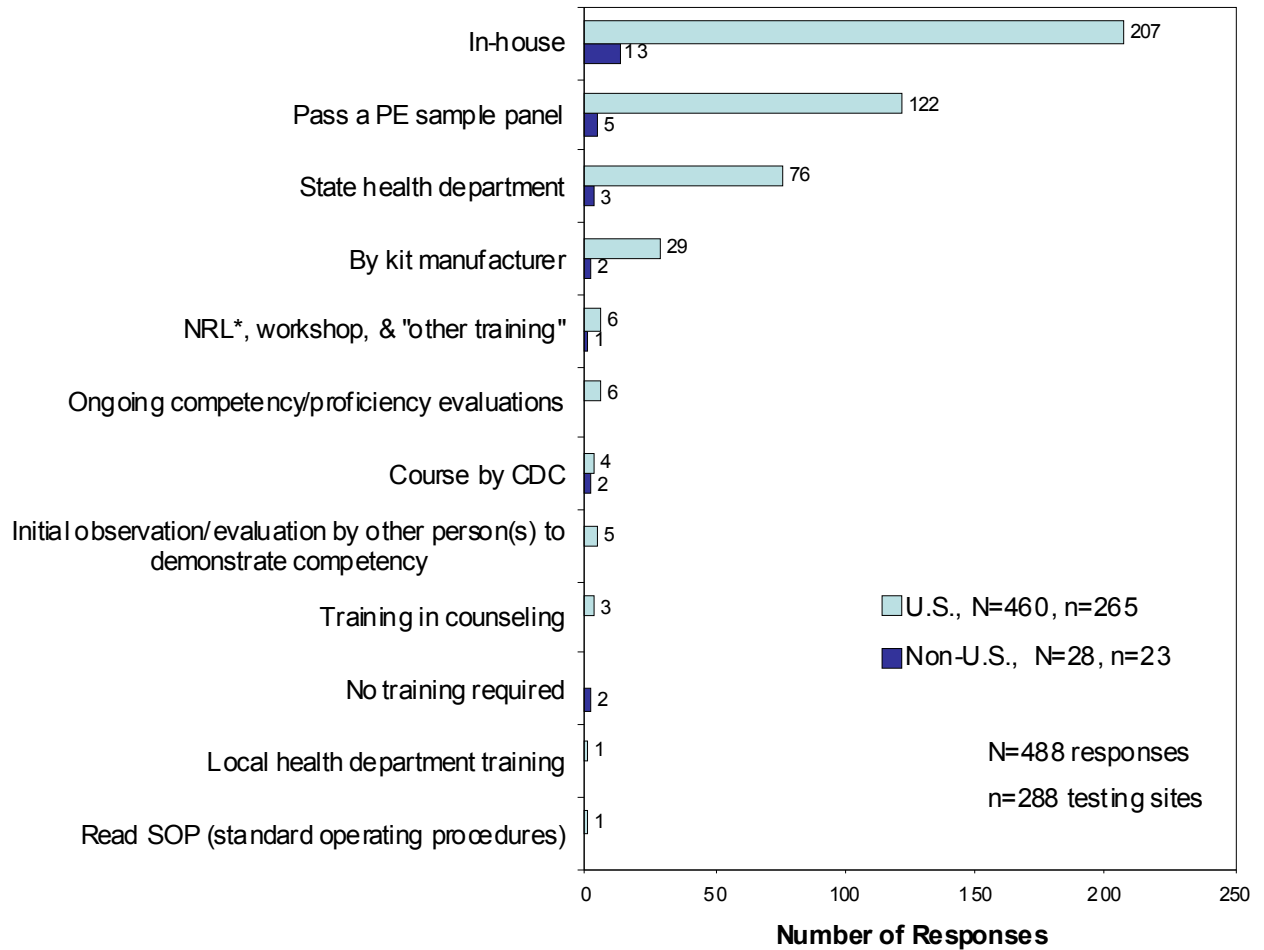
**10.) Who performs HIV rapid testing in your facility on a regular basis?
(Check all that apply).**



11.a) How many staff in your organization are trained to do HIV rapid tests?

277 sites answered the question; both U.S. (258 sites) and non-U.S (19 sites) reported varying numbers of personnel were trained to do HIV rapid testing.

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



* NRL = National Reference Laboratory

11.c) What is covered in the HIV RT training? (Check all that apply).

Facility type (n=283 respondents)	Number of responses for material(s) covered in training						
	Reading package insert	Practice test	Standard operating procedures (SOP)	External Quality Assessment (EQA)	Quality control issues	Quality assurance	Counseling
Hospital (n=131)	106	113	115	98	117	7	1
Health department (n=38)	34	34	38	31	36	4	1
Community based organization (CBO) (n=31)	29	31	31	24	29	1	2
HIV counseling and testing site (n=30)	27	28	28	28	30	3	2
Other facility type (n=7)	7	7	7	6	7		
Physician's office (n=8)	8	8	8	6	8		
Blood bank (n=9)	8	8	9	8	8		
Independent laboratory (n=7)	7	5	6	4	6	2	
Family planning center (n=10)	10	9	10	3	8		
Alternative sites* (n=12)	12	12	12	11	11		
Totals	248	255	264	219	260	17	6

* Alternative sites include: HMO, medical examiner, STD clinic, correctional facility, drug treatment center and mobile unit

Most Frequent Combinations of Answers for 11c		
Combination	Number of testing sites	% Sites (out of 283 sites)
Reading package insert, practice test, external QA and QC issues	161	57
Reading package insert, practice test, SOP, and QC issues	28	10
Reading package insert, Practice test, SOP, external QA, QC issues and other	12	4

11.d) Is there a 'site-specific' Standard Operating Procedure (SOP) manual for rapid testing at the testing site?

Facility type (n=289 testing sites)	Yes	No
Hospital (n=132)	128 (97%)	4
Health department (n=39)	39 (100%)	0
Community based organization (CBO) (n=32)	31 (97%)	1
HIV counseling and testing site (n=30)	28 (93%)	2
Alternative sites* (n=12)	12 (100%)	0
Family planning center (n=10)	9 (90%)	1
Other facility type (n=10)	10 (100%)	0
Blood bank (n=9)	9 (100%)	0
Physician's office (n=8)	7 (88%)	1
Independent lab (n=7)	6 (86%)	1
Totals	279 (97%)	10

*Alternative sites include: HMO, medical examiner, STD clinic, correctional facility, drug treatment center and mobile unit

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

Facility type (n=291)	Yes	No
Hospital (n=134)	124 (93%)	10 (7%)
Health department (n=38)	35 (92%)	3 (8%)
Community based organization (n=32)	30 (94%)	2 (6%)
HIV counseling and testing site (n=30)	29 (97%)	1 (3%)
Alternative sites* (n=13)	13 (100%)	
Family planning center (n=10)	10 (100%)	
Other (n=10)	10 (100%)	
Blood bank (n=9)	9 (100%)	
Physician's office (n=8)	7 (88%)	1 (12%)
Independent laboratory (n=7)	5 (71%)	2 (29%)
Total	272 (93%)	19 (7%)

*Alternative sites include: HMO, medical examiner, STD clinic, correctional facility, drug treatment center and mobile unit

12.b) Many laboratories/testing sites use multiple tests simultaneously or in a step-wise fashion to derive an initial (preliminary positive) result and/or a confirmed result.

What is the typical algorithm, or order of tests, you use for HIV rapid testing and confirmatory testing?

Note: All algorithms with three or more responses are defined in the table below; the remaining algorithms are listed as “Other algorithms” with the exception of the “RT, RT, RT” response, which is included in the table below with one response.

Algorithms for HIV Rapid Testing

Step 1	Step 2	Step 3	Step 4	Step 5	Responses		
					U.S. sites (n=231)	Non-U.S. sites (n=17)	Total (% sites) (n=248)
RT	WB				67	2	69 (28%)
RT	EIA	WB			58		58 (23%)
RT	RT/RT*	WB			27		27 (11%)
RT	RT/RT	EIA	IFA		15		15 (6%)
RT	RT	WB			13		13 (5%)
RT	RT/RT	EIA	WB		8	2	10 (4%)
RT	RT	EIA	WB		6		6 (2%)
RT	RT/RT	EIA			2	3	5 (2%)
RT	EIA	WB	IFA		4		4 (2%)
RT					1	2	3 (1%)
RT	EIA	WB	NAAT		2	1	3 (1%)
RT	RT	RT			1		1 (<1%)
Other algorithms					27	7	34 (14%)

*RT/RT = two rapid tests performed simultaneously

The question defined “Step 1” as the initial HIV rapid test performed by the site.

12.c) Please complete the table below to show the algorithm you use when the secondary or confirmatory test results are indeterminate (IND) AFTER an initially reactive (preliminary positive) result. What is the typical algorithm you use in your laboratory/testing site for HIV rapid testing and confirmatory testing?

Note: All algorithms with three or more responses are defined in the table below; the remaining algorithms are listed as “Other algorithms.”

Algorithms for HIV Rapid Testing

Step 1	Step 2	Step 3	Step 4	Step 5	Responses		
					U.S. sites (n=218)	Non-U.S. sites (n=17)	Total (% sites) (n=235)
RT	EIA	WB			39		39 (17%)
RT	WB				34	1	35 (15%)
RT	RT/RT*	WB			14		14 (6%)
RT	RT/RT	EIA	WB		9	2	11 (5%)
RT	RT	WB			10		10 (4%)
RT	WB	WB			7	2	9 (4%)
RT	RT	EIA	WB		8		8 (3%)
RT	RT/RT	EIA	IFA	WB&NAAT	8		8 (3%)
RT	EIA				7		7 (3%)
RT	EIA	WB	NAAT		5	1	6 (3%)
RT	WB	Other**			5		5 (2%)
RT	WB	NAAT			4		4 (2%)
RT	RT/RT	RT/RT	WB		4		4 (2%)
RT	RT/RT				3	1	4 (2%)
RT					3	1	4 (2%)
RT	EIA	WB	Other***		3		3 (1%)
RT	RT/RT	RT/RT	EIA	NAAT	3		3 (1%)
RT	EIA	EIA	WB		1	2	3 (1%)
RT	WB	RT/RT	WB		3		3 (1%)
RT	WB	RT	WB		3		3 (1%)
Other algorithms					45	7	52 (22%)

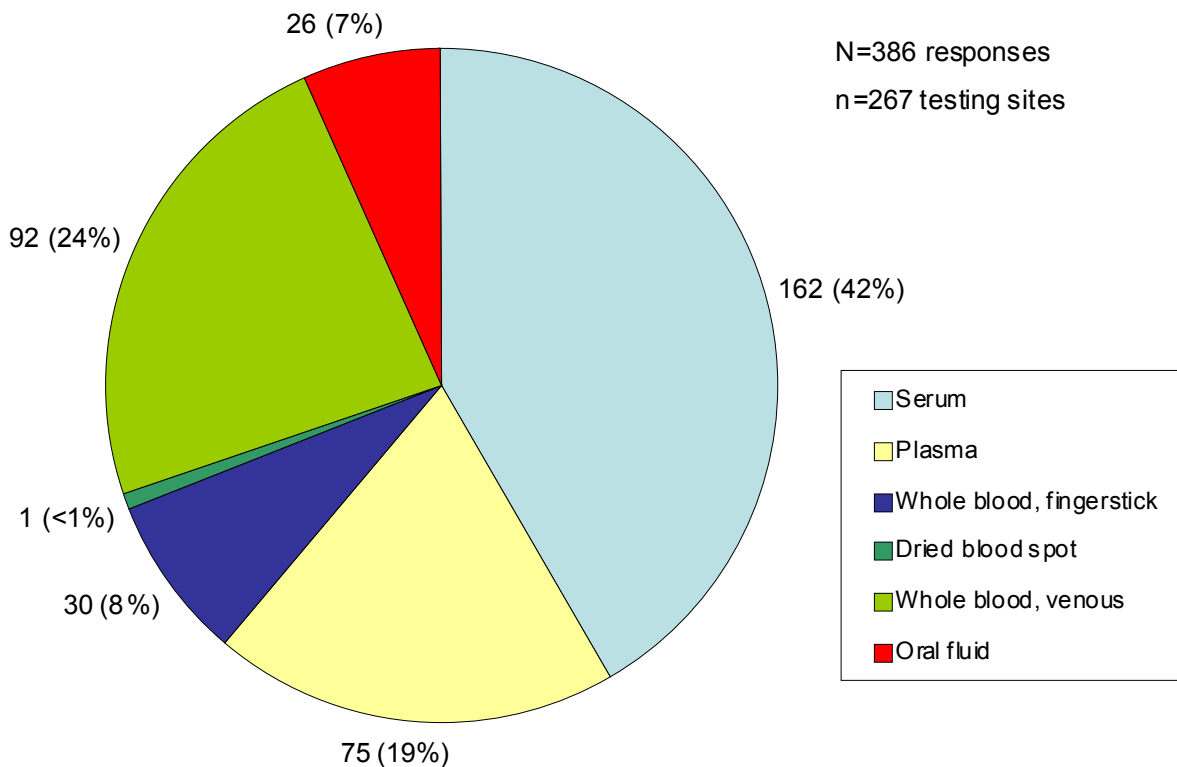
*RT/RT = two rapid tests performed simultaneously

** The “Other” tests were HIV-2 (N=2) and “not specified” (N=1)

***The “Other” tests were not specified (N=3)

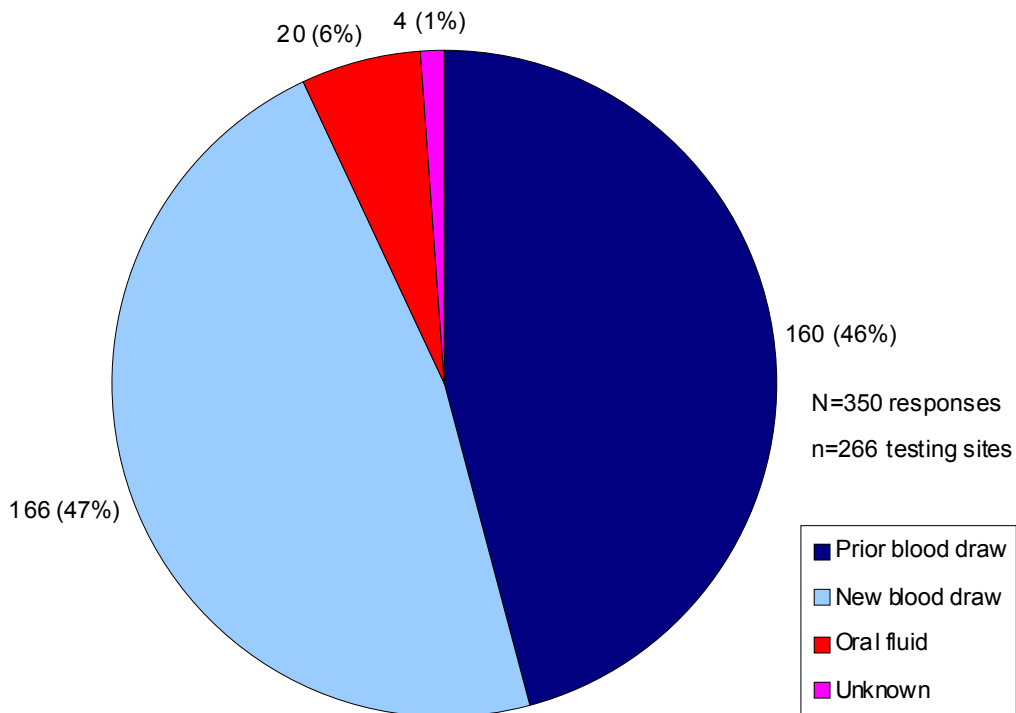
The question defined “Step 1” as the initial HIV rapid test performed by the site.

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



Note: One testing site specified “urine” as a confirmatory specimen.

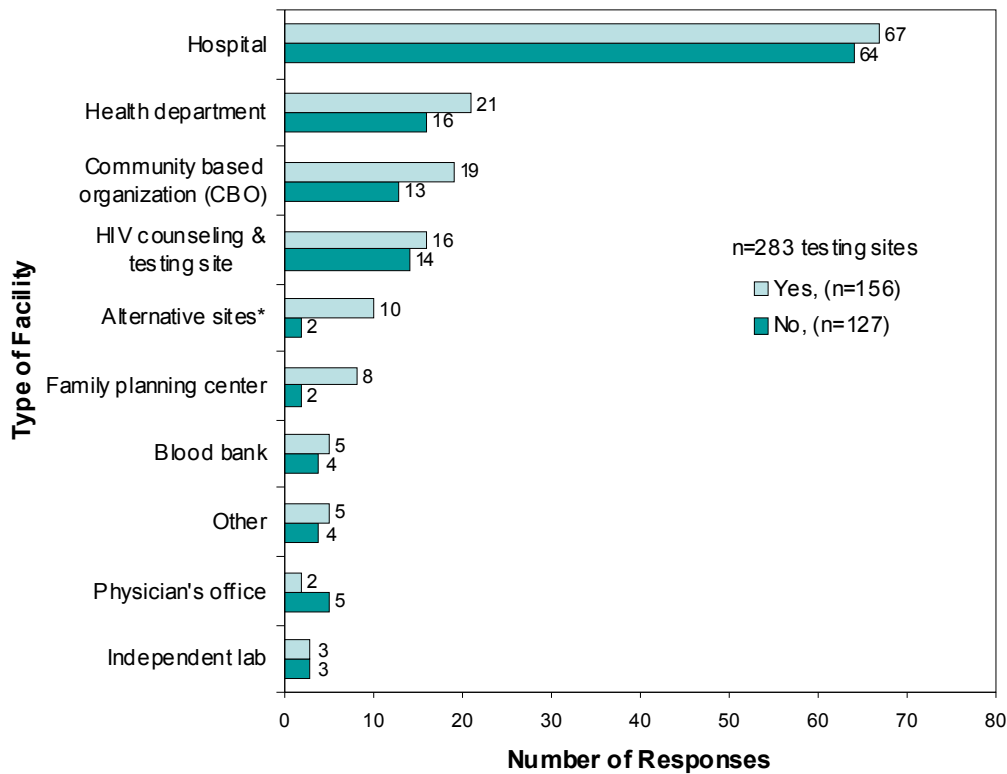
12.e) Which of the following procedures are used to obtain a specimen for a confirmatory test?



Note: One testing site specified “urine” as a procedure used to obtain a confirmatory specimen.

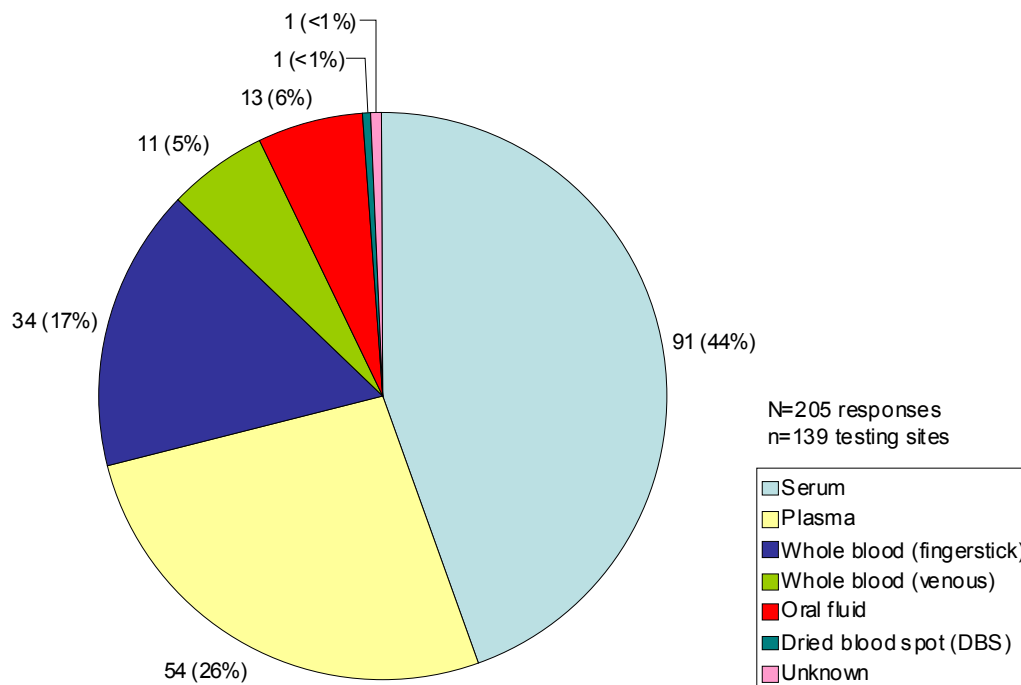
NOTE: The following three questions (12f-12h) refer to specimens which give an INITIALLY negative or indeterminate rapid test result.

12.f) If the initial HIV rapid test result is negative or indeterminate, is further HIV testing performed for that client/patient (either in your facility or another facility)?



*Alternative sites include: HMO, medical examiner, STD clinic, correctional facility, drug treatment center and mobile unit

12.g) What specimen type do you use to perform further HIV testing after an initial negative or indeterminate HIV rapid test result? (Check all that apply).

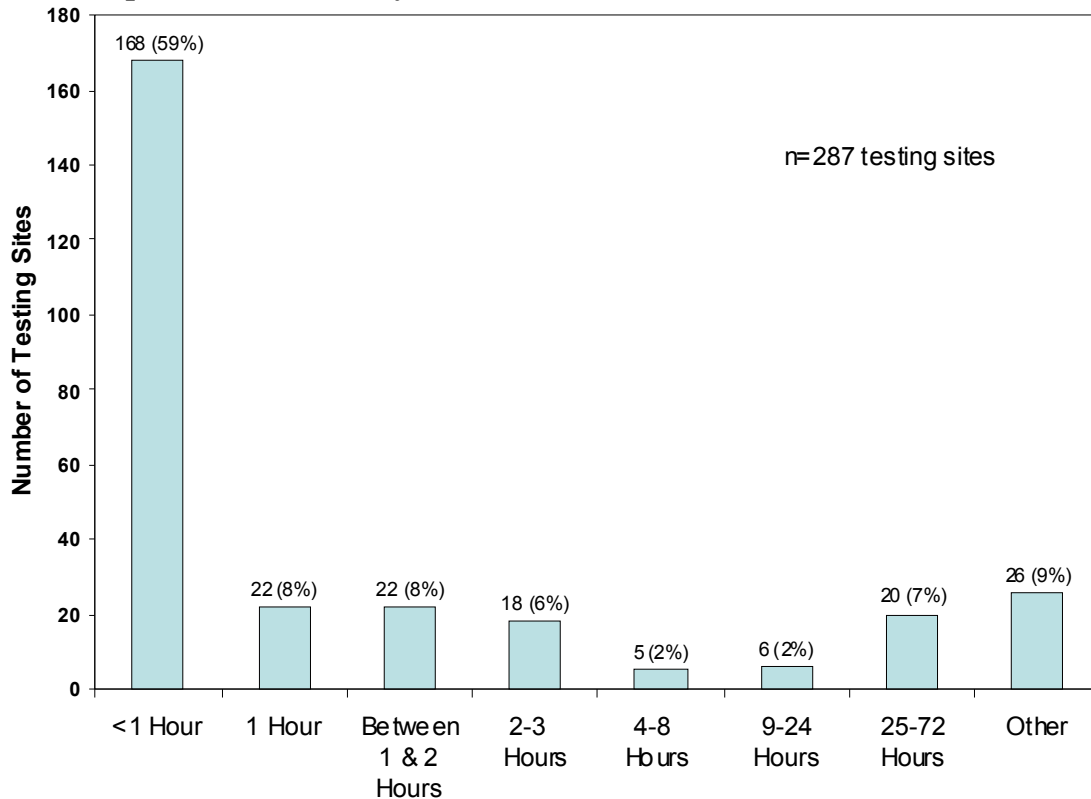


12.h) Please list in a step-wise fashion the steps you take when further HIV testing specimens which give a negative or indeterminate initial HIV rapid test result, by placing a number on the line corresponding to the step taken.

Step 1	Step 2	Step 3	Step 4	Step 5	Responses (n=158 sites)	Percentage of responses
RT	RT				32	20%
RT	RT	EIA			26	16%
RT	EIA				37	23%
RT	RT	EIA	different RT kit	2nd different RT	15	9%
RT	RT	different RT kit			13	8%
RT	different RT kit				11	7%
RT	EIA	different RT kit			7	4%
RT	RT	EIA	different RT kit		6	4%
RT	Other Algorithms				11	7%

The question defined "Step 1" as the initial HIV rapid test performed by the site.

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



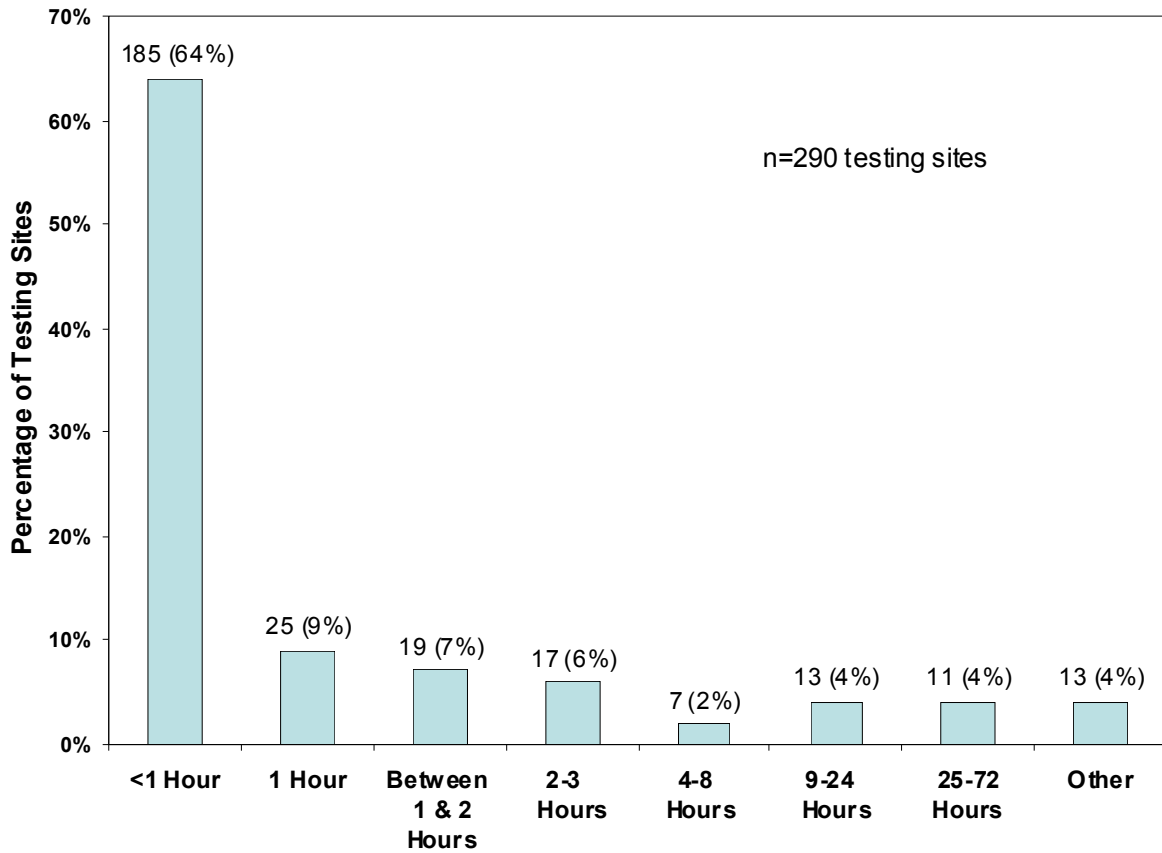
The table below outlines the responses for “Other” in the above question:

Category	Responses
Don't know/after confirmation	6
Have not had any preliminary positives	5
Don't know/tester not responsible for reporting	5
Varies with test priority (e.g. STAT vs. routine)	4
Other time: (between 72-96 hours:1, one week:1, one-two week: 1)	3
Other: n/a (1. We don't report preliminary positive result, 2. We are a company & don't have patient specimens)	2
Not specified	1

Facility type	25-72 hours	between 72-96 hours**	one week**	one-two week**
Blood bank	1			
Hospital	7			
Health department	6			1
Physician's office	2			
Counseling and testing site	2	1		
Alternative sites*			1	
Other	2			

*Alternative sites include: HMO, medical examiner, STD clinic, correctional facility, drug treatment center & mobile unit ** As specified in the “Other” option

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



The table below outlines the responses for “Other” in the above question:

Category	Responses
Varies with test priority (e.g. STAT vs. routine)	8
Unknown: tester not responsible for reporting	3
Other time: (one week:1, one-two week: 1, 72-96 hours: 1; 5 days:1)	1
Other: n/a (we are a company and don't have patient specimens)	1

14.a) For Initially Reactive (preliminary positive) HIV rapid test results, is this test result given the same day to the client/patient (the person whose sample was tested for HIV)?

Of the 293/298 sites currently performing HIV rapid testing that answered the question:

- 203/293 (69%) responded that they reported initially reactive results the same day.
- 61/293 (21%) responded that they do NOT report initially reactive results the same day.
- 29/293 (10%) responded that they did not know.

14.b) If “yes” to part (a): Who gives the result of the HIV rapid test to the client/patient (the person whose sample was tested for HIV)? (Check all that apply).

Result Provider	Responses (n=203 sites)	% Responses
The person who performed the test	109	42%
The client/patient's doctor or other health care professional	96	37%
A counselor (who did NOT perform the test)	47	18%
HIV/program specialist/coordinator	3	1%
Unknown	2	<1%
Employee health nurse	1	<1%
Total responses	258	

14.c) If “no” to part (a), (Check all that apply).

If initially reactive results are NOT given to the client/patient on the same day, then:

	Responses (n=56 sites)
Initially reactive HIV rapid test results are NOT reported directly to the client/patient; they are reported after confirmation	37
Initially reactive HIV rapid test results are reported to the client/patient's physician or health care provider	29
Initially reactive HIV rapid test results are reported to employee/occupational health OR infection control	25
Initially reactive HIV rapid test results are NOT reported to the client/patient	16
Total responses	107

Note: Of the 61 testing sites that answered “No” to question 14a, five sites gave no response to question 14c.

The sites that selected “Initially reactive HIV rapid test results are NOT reported to the client/patient” (4th category in above table) are identified by type of facility in the table below:

Facility type	Responses
Hospitals	11
Health department	1
Community based organization (CBO)	1
Independent	1
Physicians office	1
Other	1

14.d) Where do the reporting procedures for initially reactive (preliminary positive) HIV rapid tests occur? (Check all that apply).

Location of reporting procedure	Responses (n=272 sites)	% Responses
In our facility, in the dept where HIV testing is performed	220	74%
At another area of our facility (NOT the site where testing is performed)	48	16%
Externally (NOT at our facility)	23	8%
Unknown	5	2%
Total responses	296	

The sites that selected “Externally (NOT at our facility)” are identified by type of facility in the table below:

Facility type	Responses
Community based organization (CBO)	9
Health department	6
Hospitals	3
Counseling and testing site	4
Independent	1

14.e) Do you have the same test result reporting procedures for all Reactive (preliminary positive) HIV rapid tests? (Check only one).

Same reporting procedures for all reactive tests?	Responses (n=286 sites)
Yes	243
No, our result reporting procedures depend on the purpose for which the HIV rapid test is ordered	29
I do not know the reporting procedures for reactive HIV rapid tests	14

15.a) For NON-Reactive (Negative) HIV rapid tests, is this test result given the same day to the client/patient (the person whose sample was tested for HIV)?

For non-reactive tests, is the result given the same day?	Responses (n=295 sites)
Yes	235 (80%)
No	34 (12%)
Unknown	26 (9%)

The tables below compare the practices of reporting preliminary positive results (question 14a) with the reporting of non-reactive results (question 15a).

YES, initially reactive test results are given to patient/client on same day

Non-reactive test results are given the same day	Responses (n=203)
Yes	201 (99%)
No	1 (<1%)
I don't know	1 (<1%)

NO, initially reactive test results are NOT given to patient/client on same day

Non-reactive test results are given the same day	Responses (n=61)
Yes	25 (41%)
No	31 (51%)
I don't know	5 (8%)

I DON'T KNOW if initially reactive test results are given to patient/client on same day

Non-reactive test results are given the same day	Responses (n=29)
Yes	7 (24%)
No	2 (7%)
I don't know	20 (69%)

15.b) If “yes” to question 15a: Who gives the result of the HIV rapid test to the client/patient (the person whose sample was tested for HIV)? (Check all that apply)

Result provider	Responses (n=233 sites)	% Responses
The client/patient's health care provider	118	40%
The person who performed the test	113	38%
A counselor (who did not perform the test)	57	19%
Other*	6	2%
Unknown	4	1%
Total responses	298	

Note: Of the 235 sites that answered “Yes” to question 15a; two sites gave no response to question 15b.

*Of the 6 facilities that responded “Other”:

- 3 facilities indicated that the results are given by the HIV program specialist/coordinator,
- 2 facilities indicated that the results are given by the employee health nurse, and
- 1 facility indicated that the person can vary.

15.c) If “no” to question 15a, please check all that apply:

Non-reactive test results are not given to the client/patient on the same day as the test:

	Responses (n=28 sites)*
Non-reactive HIV test results are reported to the client/patient's physician or health care provider	22
Non-reactive HIV results are reported to employee/occupational health OR infection control	19
Non-reactive HIV test results are NOT reported to the client/patient	8
Other non-reactive result reporting procedure	2
Total responses	51

*Note: Of the 34 sites that answered “no” to question 15a, six sites gave no response to question 15c.

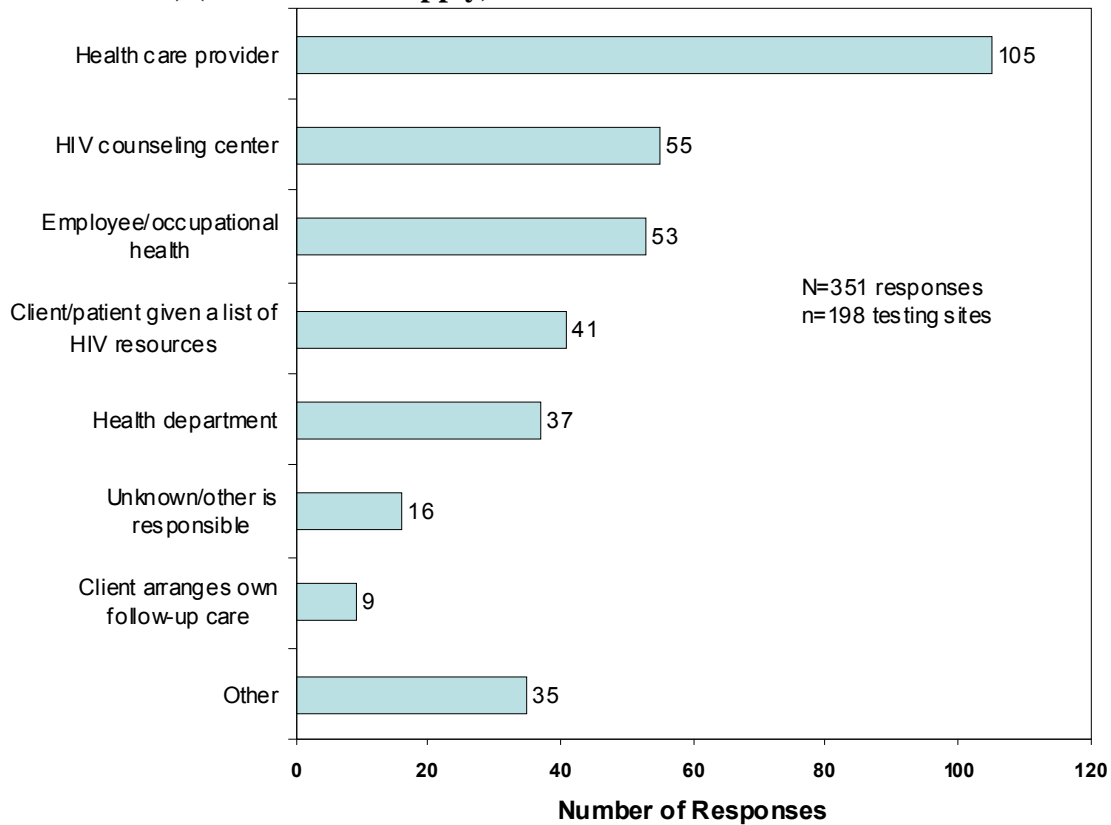
15.d) Where do the reporting procedures for non-reactive (negative) HIV rapid tests occur? (Check all that apply).

Location of reporting procedure	Responses (n=271 sites)	% Responses
In our facility, in the department where testing is performed	223	76%
At another area of our facility (NOT the testing site)	43	15%
Externally (NOT at our facility)	20	7%
I don't know	7	2%
Total responses	293	

15.e) Do you have the same test result reporting procedures for all non-reactive (negative) HIV rapid tests? (Check only one).

Same reporting procedures for all non-reactive tests?	Responses (n=286 sites)
Yes	251
No, our result reporting procedures depend on the purpose for which the HIV rapid test is ordered	27
I do not know the reporting procedures for non-reactive HIV rapid tests	8

16.a) For initially reactive (preliminary positive) HIV rapid tests, what is the typical referral procedure for the client/patient (the person whose sample was tested for HIV?) (Check all that apply).



There were 77 testing sites that responded they had no referral procedure.

The table below outlines the responses for “Other” in the above question:

Category	Responses
Not defined	19
Case management	8
Mental health services	2
Infectious disease/HIV clinic	2
Medical director for unassigned patient	1
Tribal health	1
Our clinic	1
N/A: our testing does not involve patients	1

16.b) For confirmed positive HIV rapid test results:

If a client/patient has a preliminary positive rapid test that is confirmed positive, is there a formal or informal protocol to refer this client/patient for follow-up care (medical, counseling, etc.)? (Check all that apply).

Facility type	Yes	No
Hospital (n=117)	98 (84%)	19 (16%)
Health department (n=36)	32 (89%)	4 (11%)
Community based organization (CBO) (n=31)	30 (97%)	1 (3%)
HIV counseling and testing site (n=30)	30 (100%)	
Alternative sites* (n=11)	11 (100%)	
Family planning center (n=10)	9 (90%)	1 (10%)
Other (n=10)	9 (90%)	1 (10%)
Physician's office (n=8)	6 (75%)	2 (25%)
Blood bank (n=8)	6 (75%)	2 (25%)
Independent laboratory (n=5)	4 (80%)	1 (20%)
Total n=266	235 (88%)	31 (12%)

*Alternative sites include: HMO, medical examiner, STD clinic, correctional facility, drug treatment center and mobile unit.

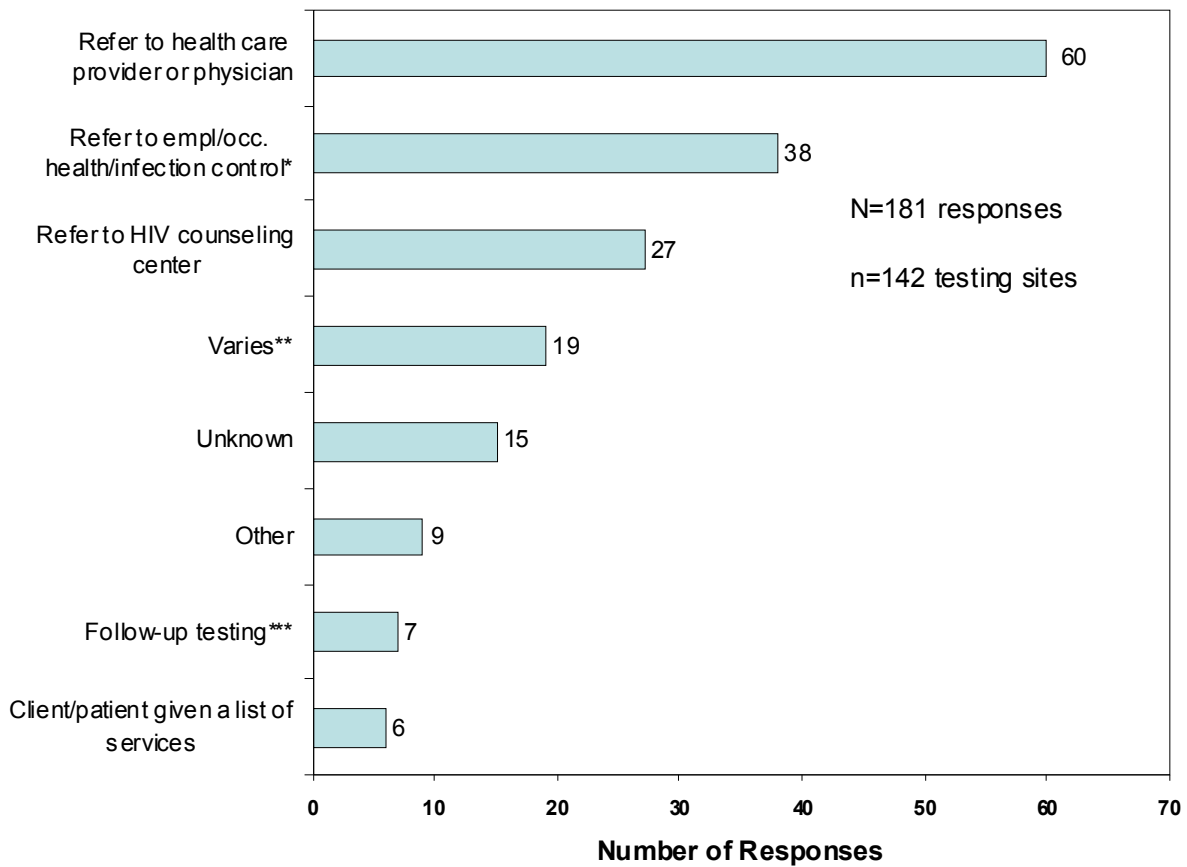
If “Yes”, i.e. there is a protocol for referral to follow-up care after a confirmed positive HIV rapid test, which of the following options does the protocol include? (Check all that apply).

Referral protocol for confirmed positive	Responses (n=205 sites)	% Responses
Health care provider	154	31%
Given list of HIV resources	81	16%
Counseling center	75	15%
Health department	71	14%
Employee/occupational resources	63	13%
Arranges own follow-up care	23	5%
Follow-up/referral	10	2%
Unknown/other is responsible	8	2%
Other	9	2%
Total	494	

Note: Of the 235 sites that answered “Yes” to question 16b, 30 sites gave no response specifying referral protocol.

16.c) For NON-REACTIVE HIV rapid test results:

**What is the typical referral procedure for the client/patient tested?
(Check all that apply)**



Note: There were 132 sites that responded they had no referral procedure.

* Refer to employee/occupational health/infection control

** "Varies" includes: varies by client, depends on clients' needs, depends on whether test is for high risk vs. low risk client.

*** "Follow-up testing" includes: follow-up testing referral, counseling and post-window testing.

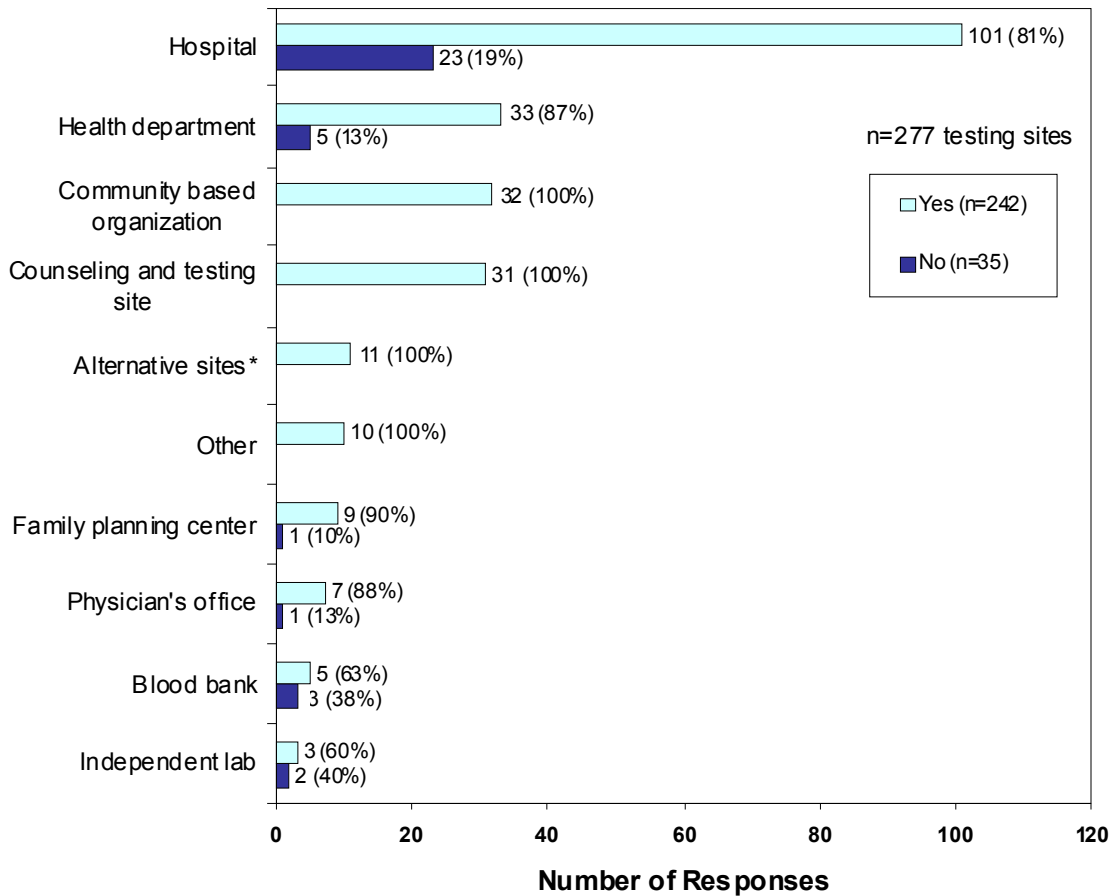
The following table outlines the "Other" responses for the above question:

Category	Responses
Prevention counseling	2
University	2
N/A testing does not involve patients	1
Infectious disease, HIV clinic or infection control	1
Support group	1
Social services	1
STD clinic and/or van	1

17.a) Does your facility/testing site provide onsite HIV counseling to clients/patients?

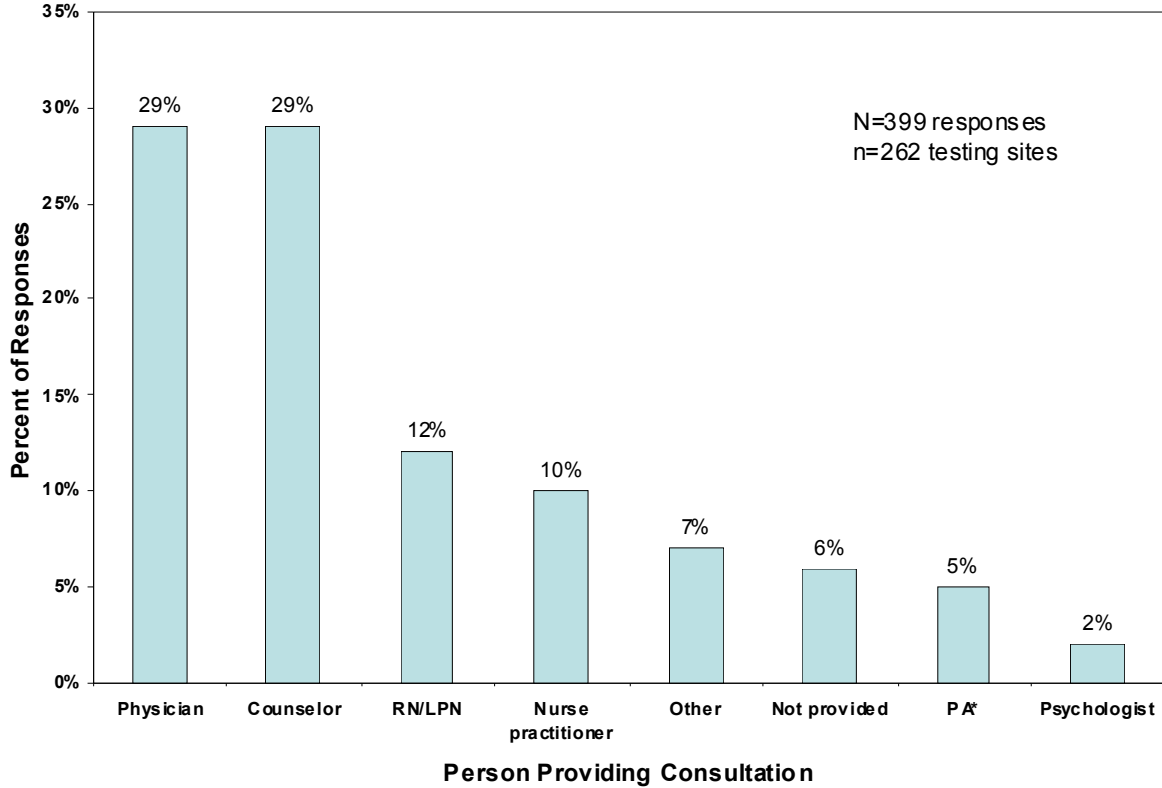
Of the 277/298 sites currently performing HIV rapid testing that answered the question, there were:

- 242 (87%) “Yes” responses, and
- 35 (13%) “No” responses.



*Alternative sites include: HMO, medical examiner, STD clinic, correctional facility, drug treatment center and mobile unit.

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

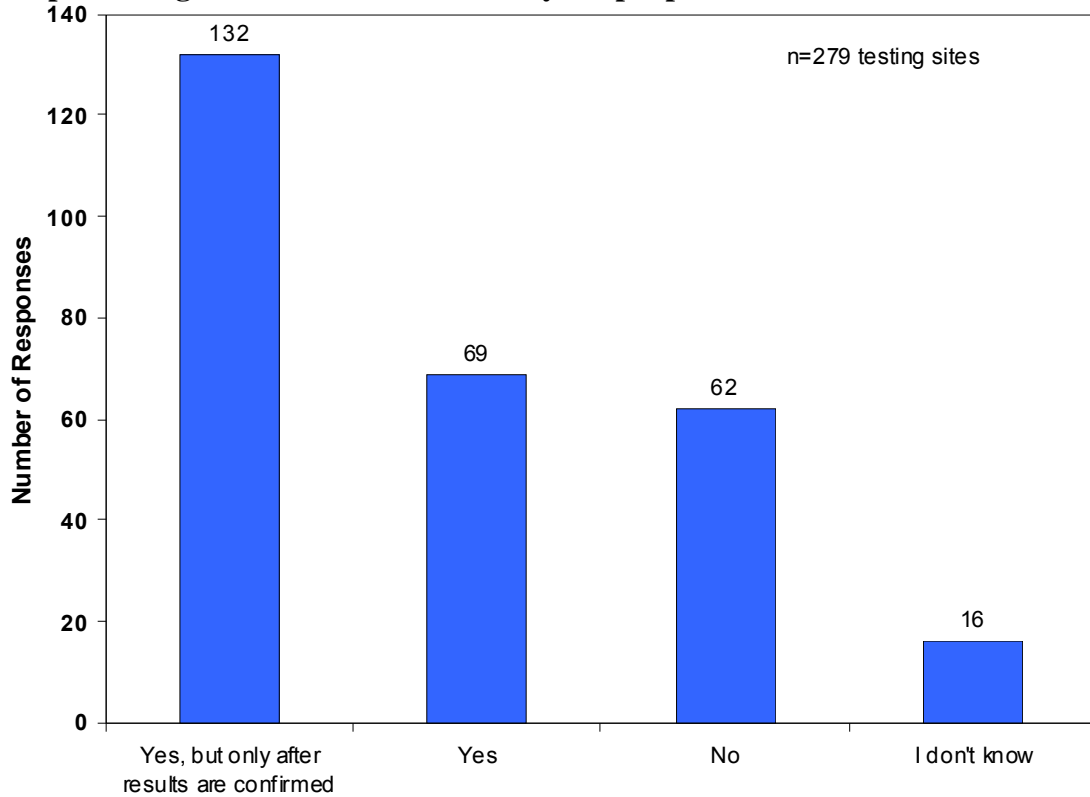


*PA = Physician's Assistant

The following table outlines the “Other” responses for the above question:

Category	Number of responses
Unknown	7
Disease intervention, infectious disease, HIV clinic, or infection control	5
Other staff: volunteer, medical assistant, mobile advocate, virologist, microbiologist, or social worker	5
Project, lab or case director, manager, or administrator	4
HIV program specialist/coordinator	2
Trained worker: outreach and/or peer education	2
Employee health nurse or other staff	1

18.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?



If “Yes”, is reporting for surveillance mandatory (see table below)?

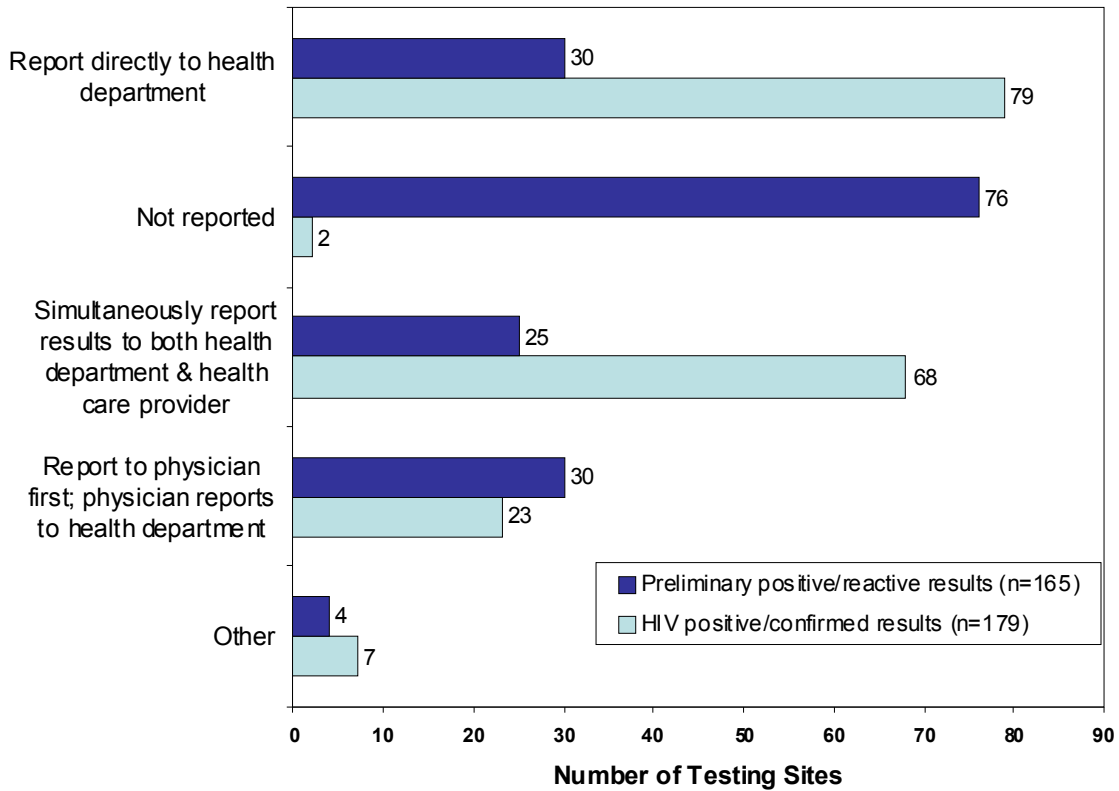
Facility type	Yes, reporting is mandatory (n=144)	
	Yes, for preliminary positive HIV-RT tests (n=40)	Yes, for confirmed positive HIV-RT tests (n=104)
Hospital	18	42
Health department	6	18
Community based organization (CBO)	6	16
HIV counseling and testing site	7	12
Alternative sites*	2	6
Blood bank	1	4
Other		3
Independent laboratory		1
Family planning center		1
Physician's office		1

*Alternative sites include: HMO, medical examiner, STD clinic, correctional facility, drug treatment center and mobile unit.

Of the 201 sites that report reactive HIV rapid tests for surveillance purposes,

- 3 sites responded that their surveillance reporting is not mandatory, and
- 54 gave no response to question about whether or not their surveillance is mandatory.

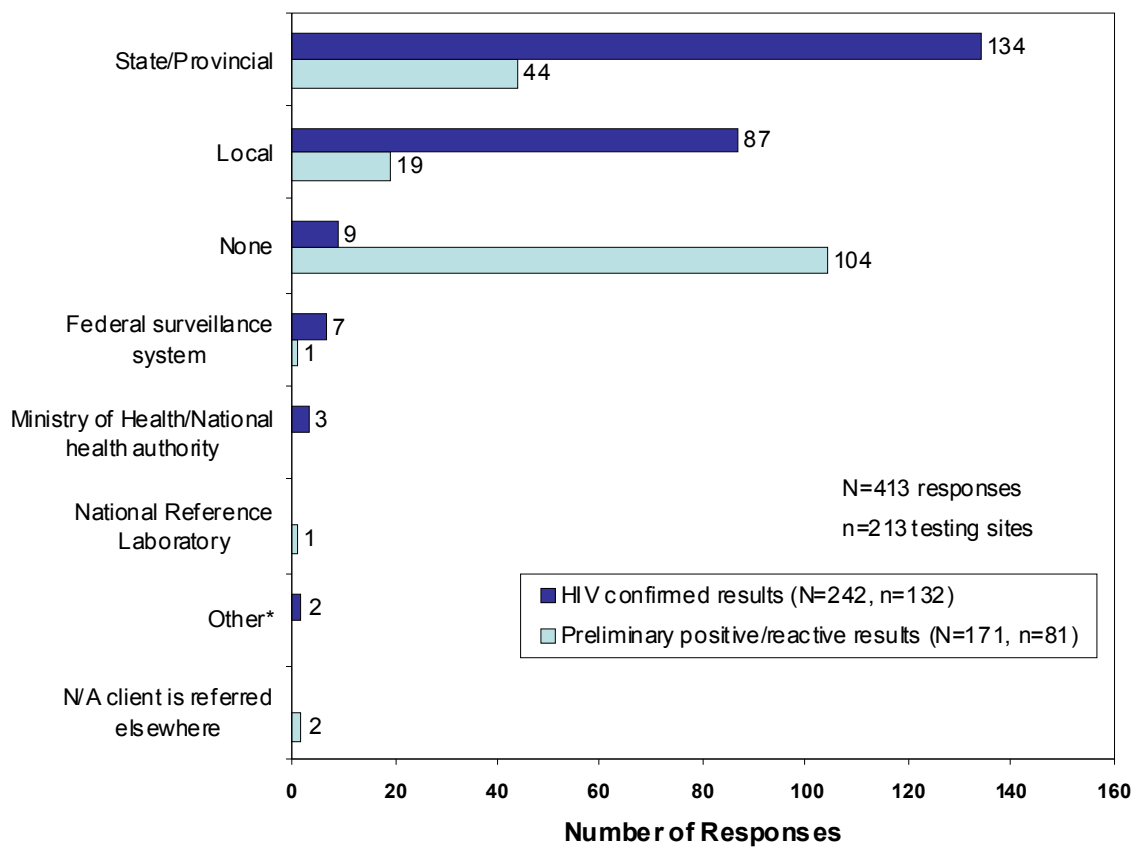
18.b) What is the typical HIV rapid testing results reporting procedure for the purposes of HIV surveillance? (Check one best answer for each column).



The following table outlines the “Other” responses to the above question:

Category	Responses
Results reported to doctor only	5
University	3
If the patient/client does not return for confirmatory testing, the preliminary results are reported to the health department	2
Uniform Reporting System (URS) Data Collection for AIDS Institute	1

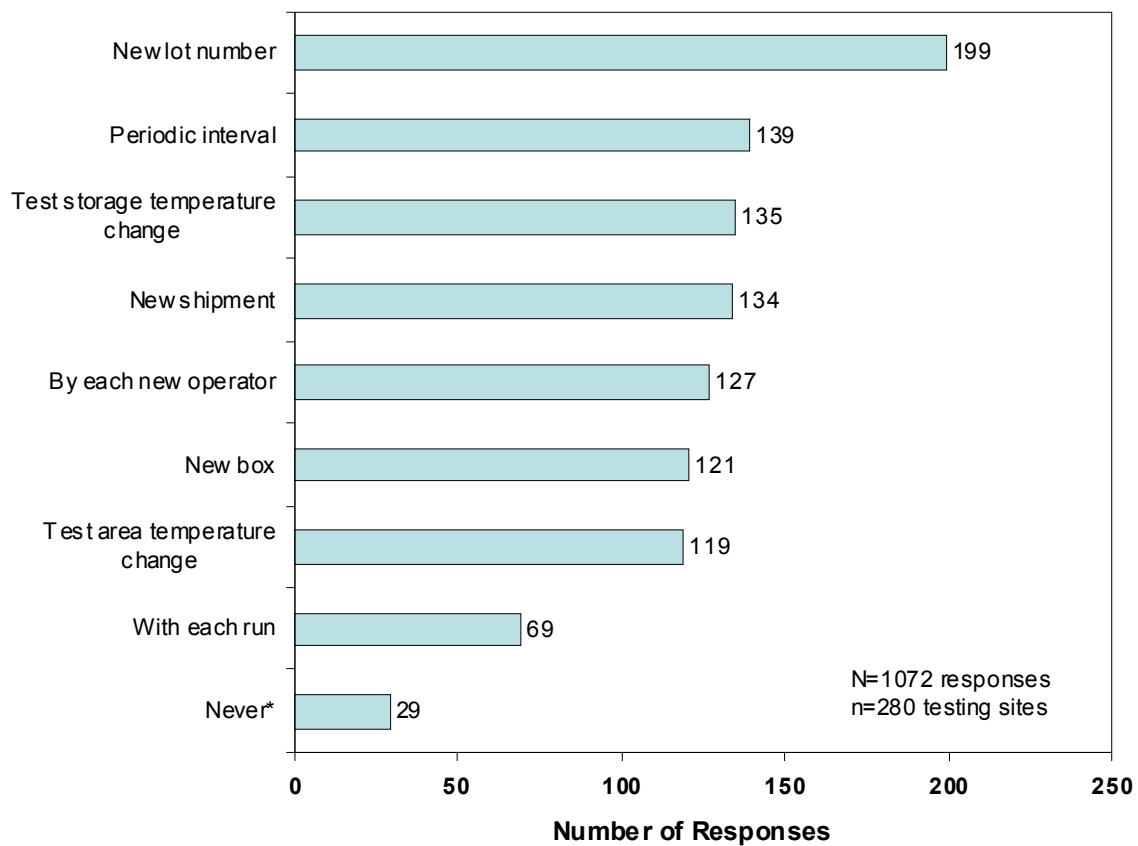
**18.c) To which health department(s) do you report HIV rapid testing results?
(Check all that apply, for each column).**



* “Other” values:

- University
- Unknown, done by reference laboratory performing testing

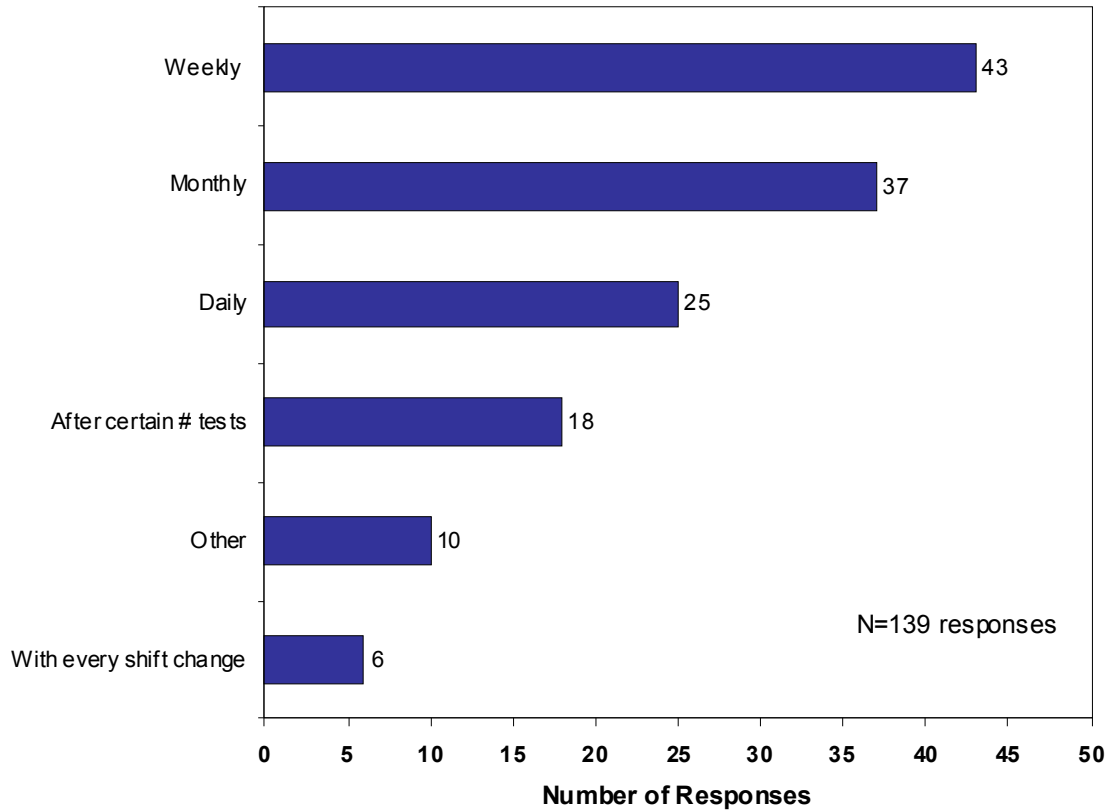
19.a) How often does your facility/testing site run control material purchased separately (positive or negative controls not included in the test kit) when performing HIV rapid testing? (Check all that apply).



*Most of these responses reflect the use of HIV rapid test kits that include quality control material as part of the kit.

19.a) continued;

The following graph details the time periods for those who specified that they run quality controls at periodic intervals.



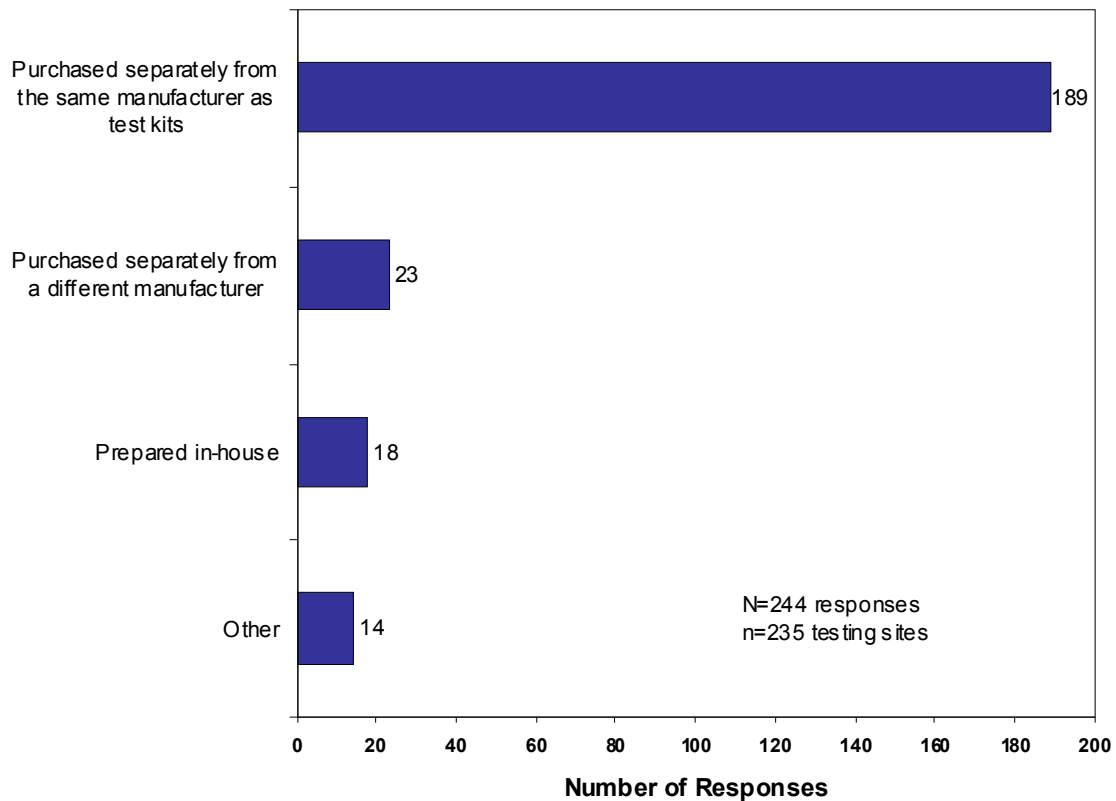
The following table outlines the “Other” responses for the “periodic intervals” category in the above question:

Category	Responses
Other time period; every: 2 weeks, 2 months, quarterly	4
Every day of testing (not same as daily)	3
As needed	1
Other number tests: if > 25 tests/shift,	1
When we have unusual, unexpected, or invalid test results	1

The table below shows the top three response combinations of quality control use:

Top 3 Combinations of answers for Question 19A	
Answer combinations	Responses
New operator, new lot, and new shipment	27
New operator, new lot, new box, new shipment, and weekly	9
New lot, new box, and new shipment	8

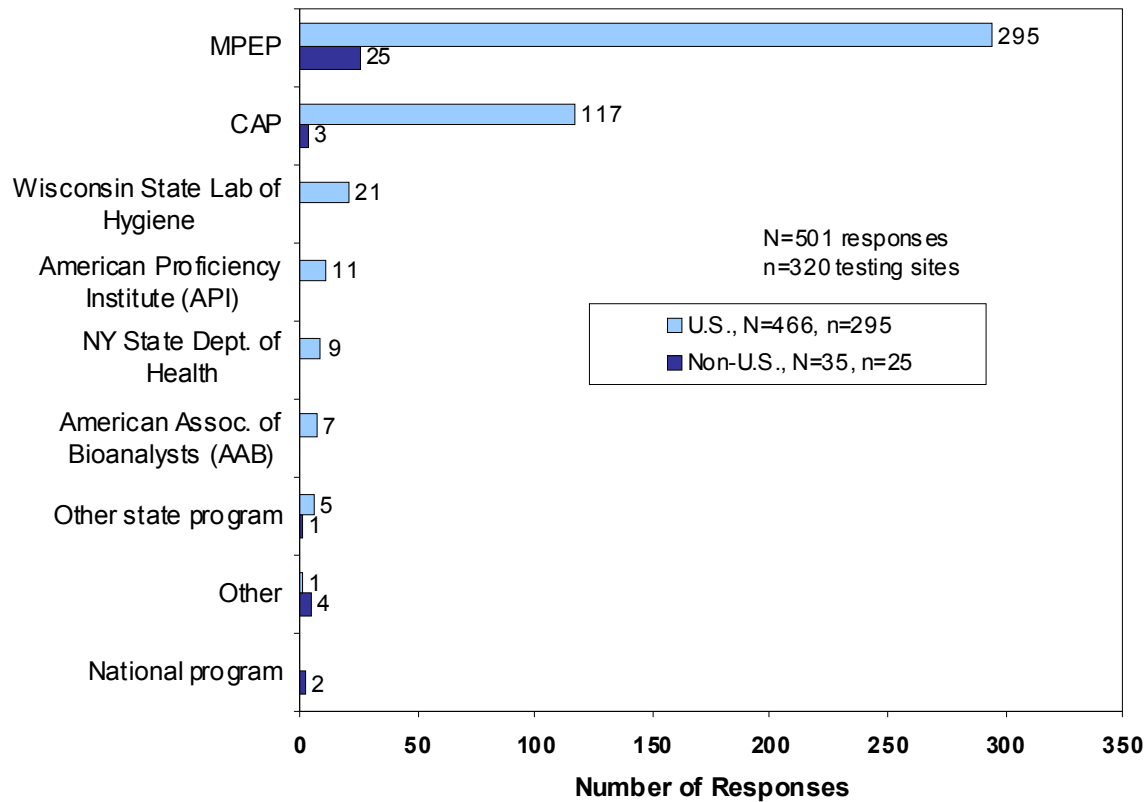
**19. b) What is the source of the control material referred to in question 19a?
(Check all that apply).**



The following table outlines the “Other” responses to the above question:

Category	Responses
Proficiency survey samples	4
State health department	4
Other QC source: NRL-Australia, NICD/WHO, ACCURUN Product	3
Unknown/not specified	3

20.a) In which external quality assurance (EQA) HIV rapid testing proficiency test (PT) or performance evaluation (PE) does your facility participate? (Check all that apply).



The following table outlines the “Other State”, “Other National” and “Other” responses to the above question:

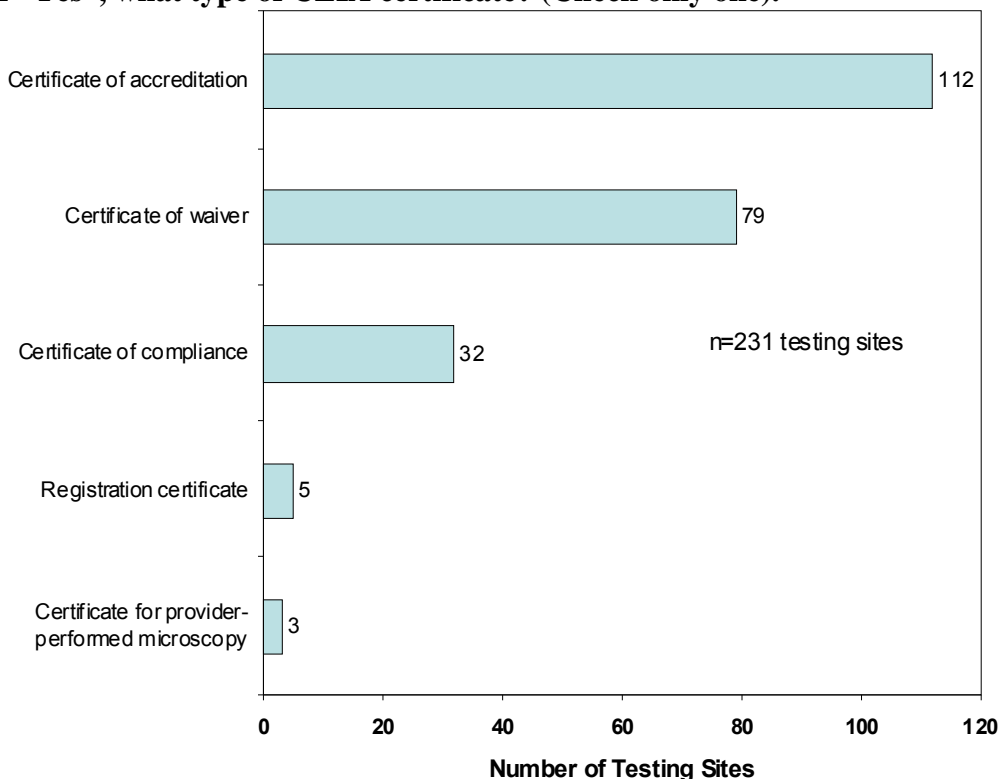
PT or PE Program	Responses
STATE Program	
Delaware	1
MDPH (Mass. Dept. of Public Health) PT Training	2
Montana Public Health Lab QA Program	1
Pennsylvania Dept. of Health	1
South Africa/WHO	1
NATIONAL Program	
Institute of Public Health in Belgium	1
Not specified	1
OTHER Program	
AFSSAPS (France)	1
Blood Center Sao Paulo Brazil	1
CTCB-Toulousian Center for Control of Biology	1
Internal PT	1
NRL - Australia	1

20.b) If you are a U.S. testing site, does your site have a government-issued CLIA certificate of waiver or another type of CLIA certificate that allows you to test?

U.S. sites with CLIA certificate	Responses
Yes	231
No	12
Total	243

Note: 31 U.S. sites currently performing HIV rapid testing did not answer the question.

If “Yes”, what type of CLIA certificate? (Check only one).

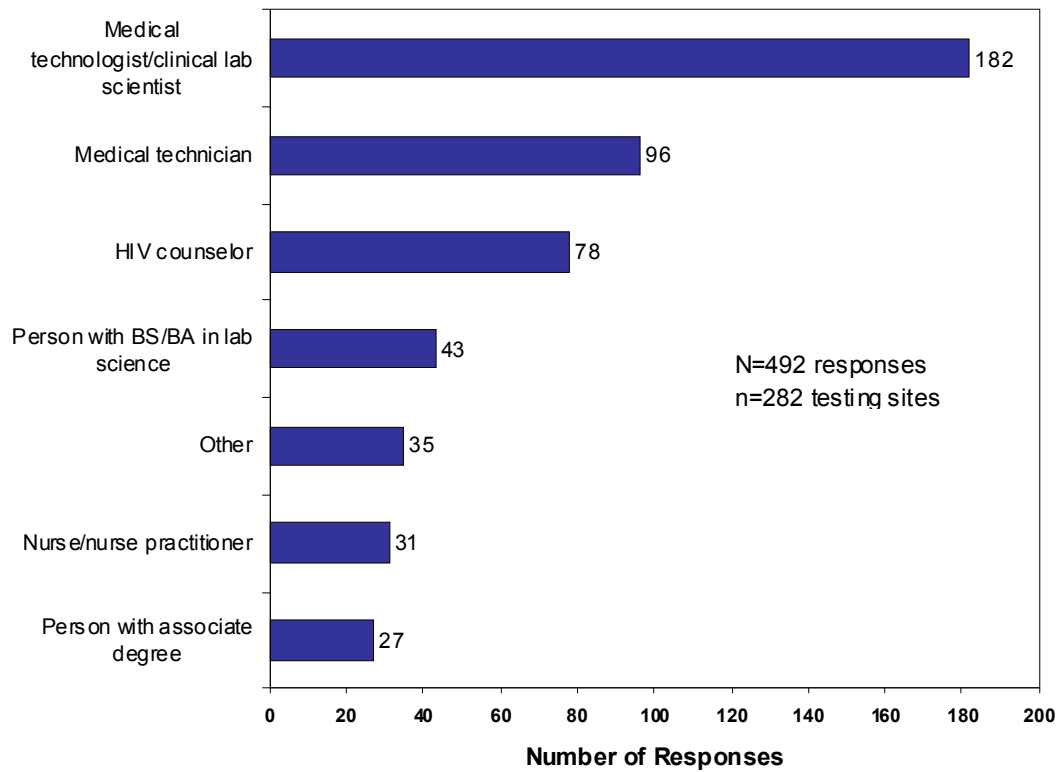


The following table shows the type of CLIA certificate by type of facility

U.S. facility type	Cert. of accreditation	Cert. of waiver	Cert. of compliance	Registration Cert.	Cert. for microscopy
Blood bank	4		9	1	
Hospital	93	5	14	3	1
Health department	2	11			
Independent laboratory	3		1		
Family planning center		3	5		
Alternative sites*	1	10	1		
Physician's office	6				
HIV counseling and testing site		22	2		2
Community based organization (CBO)	2	27		1	
Other	1	1			
Totals	112	79	32	5	3

*Alternative sites include: HMO, medical examiner, STD clinic, correctional facility, drug treatment center and mobile unit.

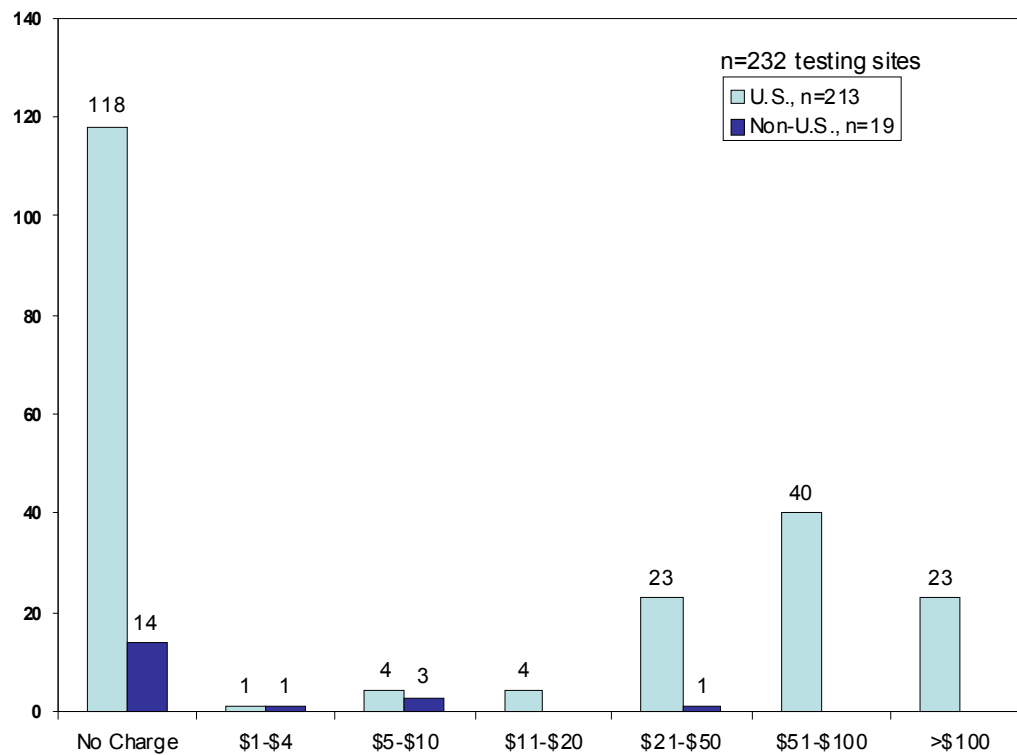
20.c) Who performs proficiency testing or performance evaluation testing for HIV rapid testing in your testing site? (Check all that apply).



The following table outlines the “Other” responses for the above question:

Category	Responses
Project, lab or case director/manager/administrator	10
Testing or site HIV coordinator	7
Phys. Asst./nurse-aide or assistant/Phlebotomist	6
MD or a person with graduate degree in lab science	2
Person with BS in community health	1
Prevention department supervisor	1
Health educator	1
State personnel from health department	1
Medical director	1
Not specified	5

**21.a) Approximately how much does your facility charge to perform an HIV rapid test?
(Round off to nearest U.S. dollar. Put \$0.00 in the box if there is no charge.)**

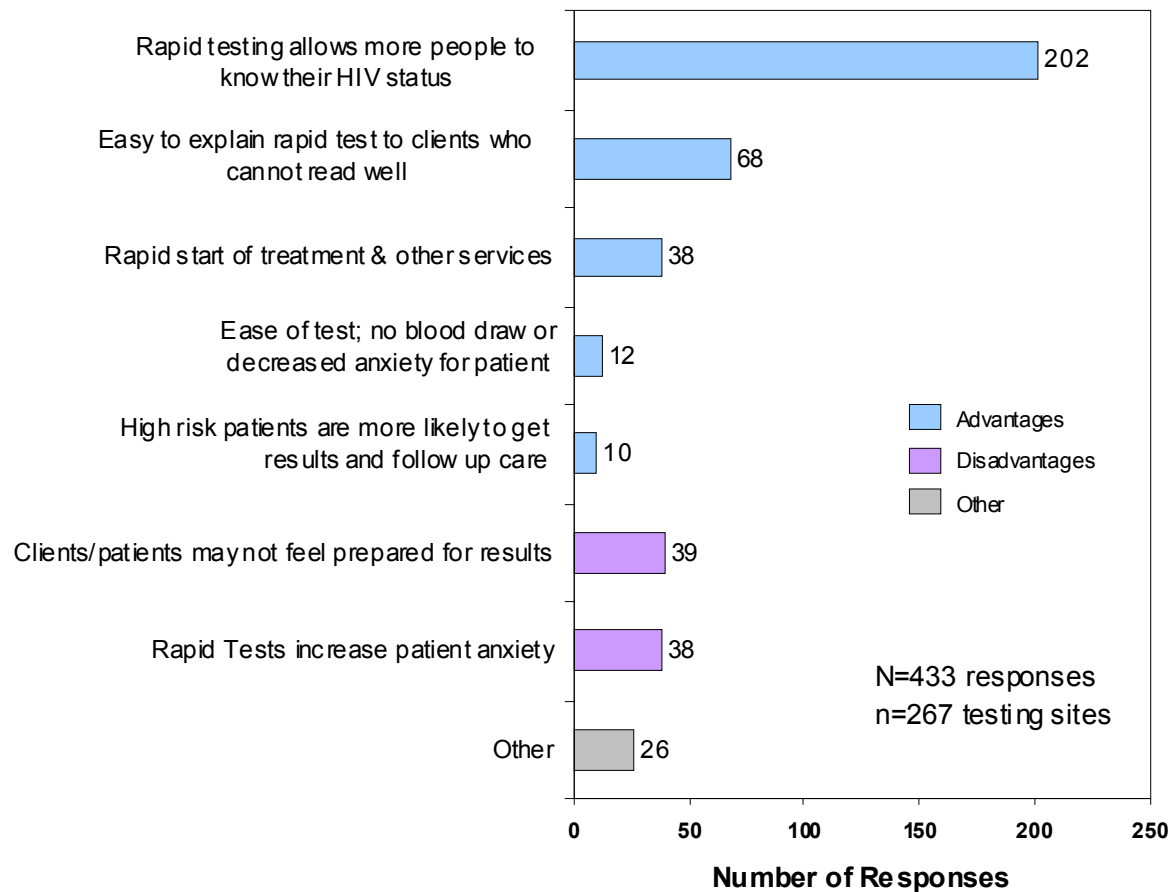


21.b) Do you accept insurance reimbursement only, so that there is no actual payment for the HIV rapid test by the client/patient?

Lab Type	Reimbursement acceptance			
	Yes	No	N/A - no charge	I don't know
Blood bank	1	3	1	2
Hospital	19	20	18	59
Health department		13	22	1
Independent laboratory	1		1	3
Family planning center	2	5	2	1
Alternative sites*		1	11	
Physician's office	4	2	1	1
HIV counseling and testing site		8	21	1
Community based organization (CBO)	2	3	27	
Other		4	4	
Totals	29	59	108	68

*Alternative sites include: HMO, medical examiner, STD clinic, correctional facility, drug treatment center and mobile unit.

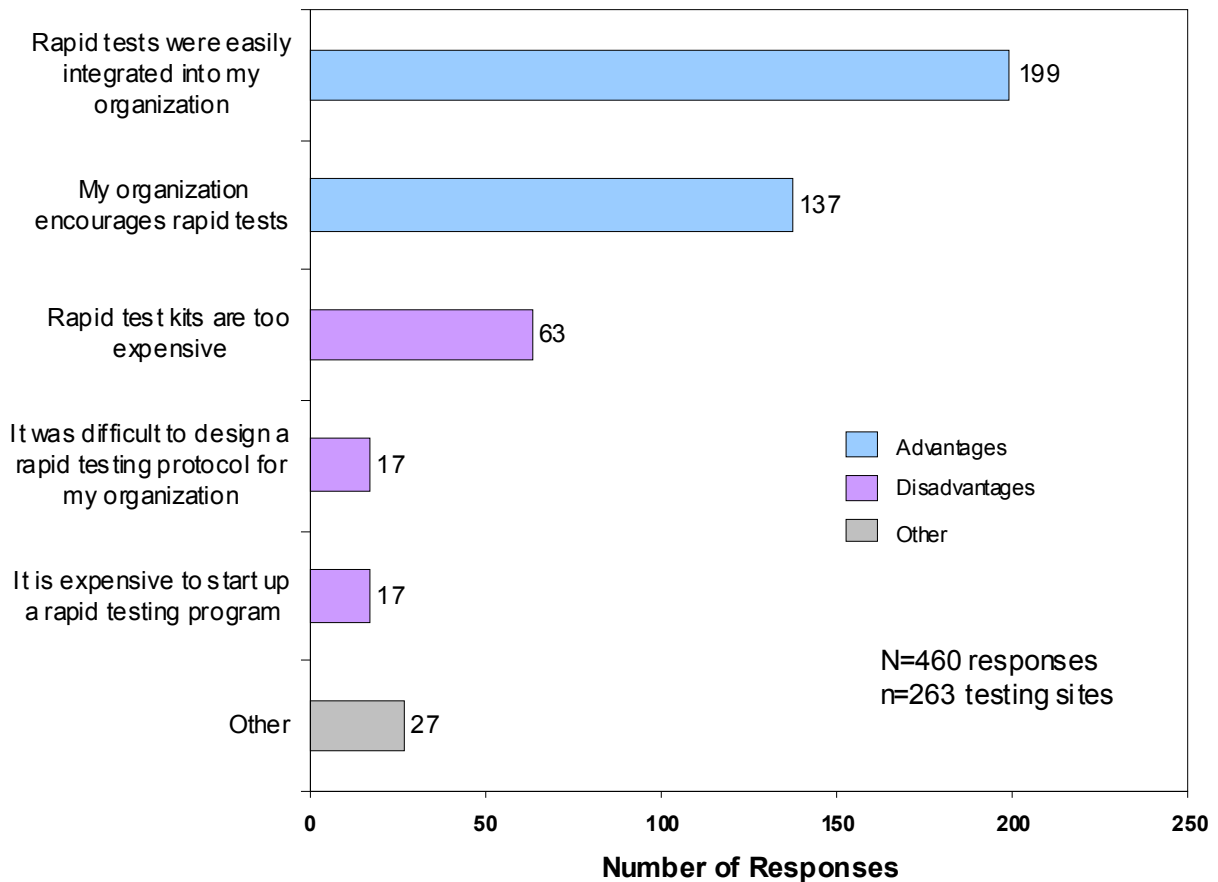
22.a) In your opinion, what are the advantages and disadvantages of HIV rapid testing for client/patients, as compared to traditional, non-rapid HIV testing? (Check all that apply).



The following table outlines the “Other” responses for the above question:

Category	Responses
No opinion; not applicable	6
Advantages	
Faster test and results; decreased waiting time	7
More convenient for patient	4
More effective in outreach settings; rapid information to health care provider; for "various" and "other" reasons	4
Low cost	1
Lower false positive than EIA	1
Disadvantages	
Higher false positives	2
Gives a false sense of security for a negative test	1

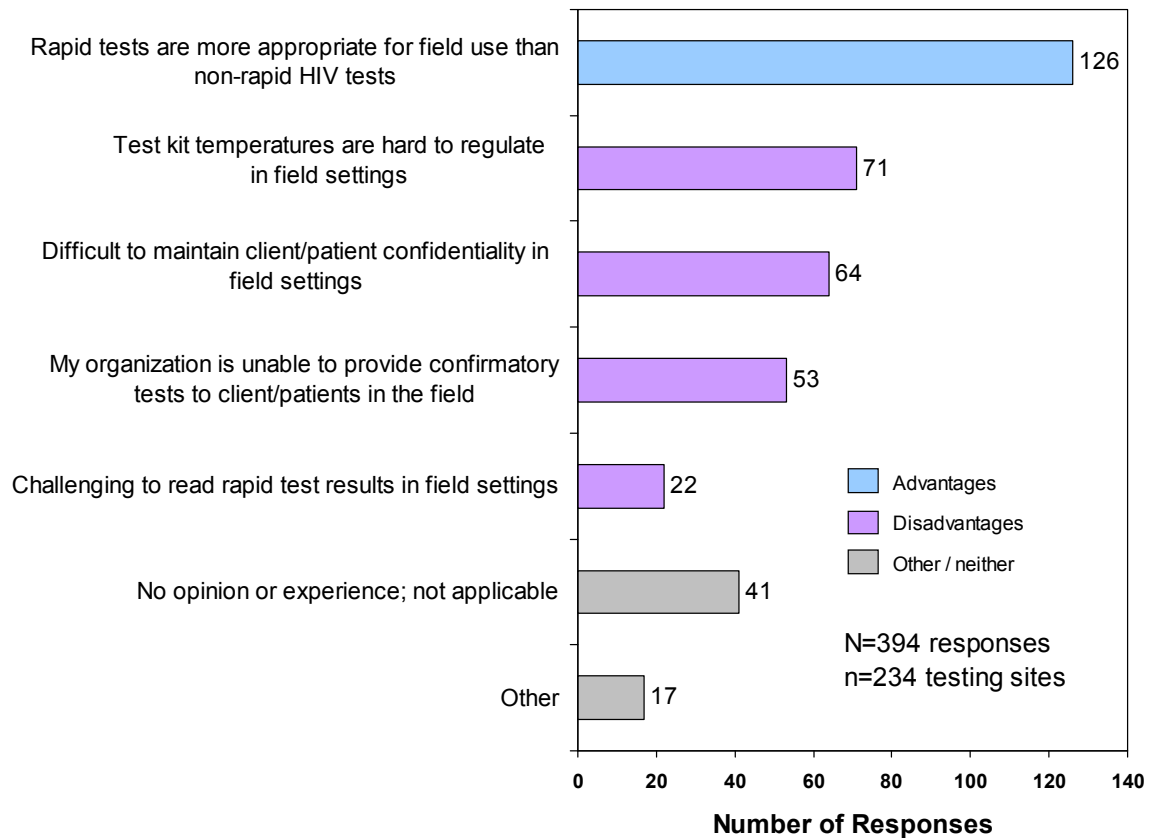
22.b) In your opinion, what are the administrative advantages and disadvantages of HIV rapid testing, as compared to traditional, non-rapid HIV testing? (Check all that apply).



The following table outlines the “Other” responses for the above question:

Category	Responses
N/a, none, no opinion or no experience	7
Advantages	
Faster results and start of analysis and/or treatment	5
Required screenings are easier (e.g. neonatal)	2
Disadvantages	
Extra cost in time/staff/paperwork especially with low volume # tests (e.g. must still do QC): i.e. overhead is more expensive	8
Transition from conventional testing is extra work	1
Problems if false positive	1
Not a routine protocol	1
Lack of sufficient training	1
Not specified	1

22.c) In your opinion, what are the administrative advantages and disadvantages of HIV rapid testing, when used in field settings such as mobile units/vans? (Check all that apply).



The following table outlines the “Other” responses to the above question:

Category	Responses
Advantage	
Reduced wait time for results; client on hand for counseling	2
Convenience to test; versatile for testing situation	2
Disadvantage	
Concerns about variable testing conditions, QC needs or documentation problems	5
Non-optimal conditions for giving results to patient. No direct access to support	3
Confirmation requires a repeat visit	2
Funding or liability concerns	2
Materials needed for both rapid testing and conventional HIV testing	1