



## **Update on Implementation of HIV Rapid Testing in Health Department Supported HIV Prevention Programs, July 2008**

### **Executive Summary**

#### **INTRODUCTION**

In late 2007, NASTAD conducted a survey of health departments to continue monitoring health department efforts to implement and support rapid HIV testing. The survey was designed to obtain a fuller understanding of the use of rapid HIV testing in conjunction with health department supported HIV prevention efforts. Specifically, this survey examined the mechanisms and resources used by health departments to procure rapid HIV test devices; the types of test technologies and volume of tests conducted by health department supported testing programs; the venues in which rapid HIV testing was conducted; and health department priorities for expansion of rapid HIV testing. This survey expands on previous survey efforts conducted in 2006 by examining issues associated with adoption of rapid HIV tests from various manufacturers, performance of rapid HIV tests and use of multi-test algorithms. The findings from this survey will contribute to the development and prioritization of technical assistance activities, guide education and advocacy efforts and contribute to the development of multi-test rapid HIV testing algorithms.

#### **METHODS**

In November 2007, AIDS directors from the 65 CDC-funded state, territorial and directly-funded city health departments were asked to participate in an on-line survey. Health departments were given two weeks to respond to the survey. Follow-up was conducted with non-responders after the close of the submission deadline. A total of 51 health departments responded to the survey including 45 of the 50 state health departments, five of the six directly-funded cities and the District of Columbia.

The survey questionnaire (Appendix A) included nineteen questions, encompassing five sections: implementation of rapid HIV testing; procurement of rapid HIV tests; rapid HIV test performance; use of combinations of multiple rapid HIV tests; and technical assistance needs.

## KEY FINDINGS AND DISCUSSION

### **Implementation and Expansion of Rapid HIV Testing**

- The vast majority 47 (94.0 percent) of health departments indicated they use rapid HIV testing in conjunction with health department supported HIV testing programs.
- Rapid HIV testing is in wide use by health departments in a variety of settings. Health departments reported a total of 3,371 unique sites operated by 1,439 agencies that provide rapid HIV testing.
  - A large majority of health departments offer rapid HIV testing in a range of community-based settings such as outreach sites (95.7 percent), community-based organizations (93.6 percent), free standing HIV test sites (93.6 percent) and local health departments (80.9 percent).
  - Many health departments offer rapid HIV testing in a variety of health care settings including sexually transmitted disease (STD) clinics (74.5 percent), substance abuse treatment centers (66.0 percent), community health clinics (53.2 percent) and hospital emergency departments (31.9 percent).
- Twenty-three health departments support routine HIV testing (i.e., screening) in health care settings and almost all (95.7 percent) reported using rapid HIV testing in conjunction with these efforts.

*The expansion of rapid HIV testing is likely due to multiple factors including health department capacity to support rapid HIV testing, decreasing cost of rapid HIV tests and increased funding for expansion of HIV testing, particularly in high volume clinical settings. Continued reductions in federal funding and increasingly constrained state and local funding make it essential to monitor this trend and, in particular, to examine the extent to which funding issues impact the adoption and expansion of HIV testing programs, specifically the uptake of rapid HIV testing.*

### **Rapid HIV Testing in the Context of Overall HIV Testing Efforts**

- Eighty-one percent of health departments reported plans to expand the number of sites offering rapid HIV testing in 2008, with a total minimum addition of 562 sites that will begin offering rapid HIV testing.
- The overall volume of rapid HIV tests conducted in health department supported programs is expected to increase from a minimum of 1,678,952 in 2006 to an estimated 2,093,339 in 2008.
  - In 2008, health departments expect that rapid HIV tests will account for 51.8 percent of all tests conducted in health department supported programs, compared with 42.2 percent in 2006.
  - Oral fluid HIV tests account for 21.5 percent of all conventional HIV tests conducted in health department supported programs.

*While rapid HIV testing appears to be increasing in prominence in health department supported HIV testing efforts, conventional HIV testing continues to play an important role in these efforts, with nearly 700,000 such tests projected for 2008. For this reason,*

*it is important for health departments to maintain and enhance capacity for laboratory-based HIV testing.*

*Oral fluid HIV testing continues to be an important technology. Development of an oral fluid screening assay is essential in order to ensure the continued capacity of health department laboratories to provide oral fluid HIV testing and to ensure the sustainability of health department HIV testing programs. It would also be highly desirable to develop an alternative oral fluid Western blot, in light of recent reports of increasing cost of this product.*

### **Selection and Utilization of Specific Rapid HIV Tests**

- Health departments reported on the types of rapid HIV tests used in their HIV testing programs. OraQuick Advance® is used by 95.5 percent of health departments; UniGold™ is used by 45.5 percent; and Clearview® is used by 20.5 percent of health departments. (Percents reflect the number of health departments using a particular manufacturers' product not the actual number of rapid HIV tests performed.)
  - Most health departments reported using multiple rapid HIV tests and many also reported, at the time of the survey, that a final decision had not been made about the specific rapid HIV test(s) they would use in 2008.
  - Price appears to be the single most important criteria used by health departments in determining which rapid HIV test(s) to use. Nearly 71 percent of respondents cited price as one of the three most important factors, and 38.6 percent cited price as the most important determining factor. Shelf life, sensitivity, ease of specimen collection and approved for oral specimens also received mention as important criteria in selection of specific rapid HIV tests.

*Price was the single most important factor cited by health departments in deciding which rapid HIV test(s) to use. Increased competition from multiple manufacturers of rapid HIV tests is expected to continue to drive down the cost of rapid HIV tests. At the same time, health departments will likely continue to deploy rapid HIV testing in a wide range of settings and for diverse populations and thus may increasingly seek to “match” test features to venues, settings and populations in order to optimize HIV testing efforts.*

### **Procurement**

- In 2007, health departments purchased 1,077,428 rapid HIV tests and they plan to purchase 1,553,858 rapid HIV tests through one or more procurement mechanisms in 2008.

*Health departments expect to increase by nearly 500,000 the number of rapid HIV tests they will purchase in 2008, compared with 2007. This is likely a reflection of increased federal funding for HIV testing coupled with the decreasing price of rapid HIV tests. Most health departments utilize their health department procurement process to purchase rapid HIV tests, which generally takes the form of a competitive bidding process.*

## **Performance**

- Through November 2007, twelve health departments reported having experienced a total of twenty clusters of false positive HIV test results in conjunction with rapid HIV testing. All the false clusters reported involved OraQuick Advance®.

*While a number of factors were thought to play a role in the clusters of false positive HIV rapid test results including over-collection of specimen, storage temperatures, operating temperatures and lot manufacture, none of the health departments responding to the survey could pin-point a single cause for the clusters. Health departments will need to continue to monitor performance of rapid HIV tests, particularly as they adopt rapid HIV tests from different manufacturers.*

## **Multi-Test Algorithms**

- Four health departments reported having implemented a sequential multi-test algorithm. Only two of these report using rapid HIV tests produced by different manufacturers.
- One health department reported having implemented a parallel multi-test algorithm.

*Development of new national guidelines which address the application of rapid HIV tests in multi-test algorithms for use in diagnosing HIV infection are needed and desired by health departments. Such guidelines may stimulate health departments to consider adopting multi-test algorithms for diagnosing HIV infection using rapid HIV technologies. At the same time, as more rapid HIV tests classified as CLIA-waived become available and the prices of testing technologies drop, more health departments may wish to explore adoption of multi-test algorithms as a means to increase the efficiency and effectiveness of HIV testing programs.*

## **Technical Assistance Needs**

- Health departments report a very limited need for basic training and skills development on the technical aspects of rapid HIV testing. Only 8.7 percent reported a need for laboratory or test device training.
- Health departments identified guidance and assistance in adopting multi-test algorithms as an important technical assistance need (45.7 percent). Technical assistance to evaluate the cost-effectiveness of rapid HIV testing (43.5 percent) and the impact of rapid HIV testing (37.0 percent) were also identified as important technical assistance needs.

*Survey findings suggest that health departments have rapidly built internal capacity for providing necessary training and technical assistance on the technical aspects of HIV testing with rapid technologies. Priority technical assistance needs identified by health departments include adoption of multi-test algorithms for diagnosing HIV-infection at point-of-care, evaluating the impact of rapid HIV testing programs and evaluating the cost-effectiveness of rapid HIV testing. This assistance would be invaluable in helping*

*health departments enhance the efficiency of HIV testing programs and optimize use of increasingly constrained resources.*

## **LIMITATIONS**

There are several limitations to these findings. All data were self-reported and are subject to the knowledge and interpretation of the individual(s) who completed the survey. Several health departments were unable to provide data related to the volume of HIV tests (both conducted and procured), so responses to these questions likely under represent the total volume of HIV tests. Questions that asked health departments to estimate the number of HIV tests to be purchased in the future should be interpreted with caution as the estimates can be influenced by multiple factors including, but not limited to, funding and implementation issues.

This survey asked health departments to provide retrospective data regarding HIV test performance. This proved challenging for health departments, particularly where data had not been compiled and managed in electronic file formats. Two health departments provided two separate sets of data which were not entirely consistent and required additional investigation to reconcile data.



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### **INTRODUCTION**

NASTAD has long supported rapid HIV testing and was among the organizations instrumental in advocating for Food and Drug Administration (FDA) approval of rapid HIV testing technology as well as the Clinical Laboratory Improvement Amendments (CLIA) waiver that allows for use without regulatory oversight, particularly in non-clinical settings. With the approval of this technology, health departments have implemented rapid HIV testing in a wide variety of settings and rapid HIV tests account for a significant proportion of all HIV tests conducted in health department supported HIV testing programs.

In late 2007, NASTAD conducted a survey of health departments to continue to monitor health department efforts to implement and support rapid HIV testing. The survey was designed to assist in obtaining a fuller understanding of the use of rapid HIV testing in conjunction with health department supported HIV prevention efforts. Specifically, the survey examined the mechanisms and resources used by health departments to procure rapid HIV test devices; the types of HIV test technologies and volume of HIV tests conducted by health department supported HIV testing programs; the venues in which rapid HIV testing was conducted; and health department priorities for expansion of rapid HIV testing. The survey was conducted as a follow-up to a similar survey conducted in 2006.

The survey expands on NASTAD's previous survey effort conducted in 2006 by examining issues associated with adoption of rapid HIV tests from various manufacturers, performance of rapid HIV tests and use of multi-test algorithms. The findings from the survey will contribute to the development and prioritization of technical assistance activities, guide education and advocacy efforts and contribute to the development of multi-test rapid HIV testing algorithms.

### **METHODS**

In November 2007, AIDS directors from the 65 CDC-funded state, territorial and directly-funded city health departments were notified, via email, of the survey effort and provided with information necessary to complete the on-line survey. Health departments were provided with a two-week period to enter survey responses. A reminder email was sent one week prior to the submission deadline. After the response deadline had passed, individual health departments that had not responded to the initial requests for response were contacted via email and phone by NASTAD staff and

consultants to encourage participation. Up to three attempts were made to encourage participation during the four weeks subsequent to the response deadline.

The survey questionnaire (Appendix A) included nineteen questions, encompassing five sections. The first section addressed implementation and examined the venues and settings in which health departments have implemented rapid HIV testing, the volume and types of HIV tests (i.e., rapid or conventional) and the specific rapid HIV tests employed in conjunction with health department supported HIV testing efforts. This section also included items which examined the factors that health departments consider in selecting which rapid HIV test(s) to use. The second section of the survey addressed procurement, including the mechanisms used by health departments to purchase rapid HIV tests. The third section of the survey addressed performance of rapid HIV tests. Included in this section were items that examined clusters of false-positive rapid HIV test results and health department efforts to investigate the causes of these clusters. The fourth section of the survey examined the use of combinations of multiple rapid HIV tests by health department supported HIV testing programs. The final section of the survey addressed health department future plans for use of rapid HIV tests and technical assistance needs associated with implementing and sustaining rapid HIV testing efforts.

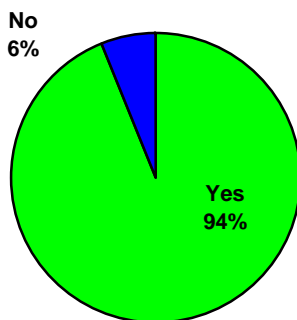
A total of 51 health departments responded to the survey including 45 of the 50 state health departments, five of the six directly-funded cities and the District of Columbia.

## FINDINGS

### Current Status of Rapid HIV Testing

Health departments were asked to indicate whether or not they currently supported a rapid HIV testing program. As indicated in Figure 1, of the 50 health departments that responded to this item, 47 (94.0 percent) indicated they supported rapid HIV testing.

Figure 1. Percent of Health Departments Supporting Rapid HIV Testing (N=50)



Only three health departments<sup>1</sup> reported that they do not currently support a rapid HIV testing program. Reasons cited for not having implemented rapid HIV testing included

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<sup>1</sup> The three health departments that were not supporting rapid HIV testing at the time of the survey were New Mexico, North Dakota and South Dakota.

lack of resources, lack of health department infrastructure and lack of local provider capacity. Two of the three health departments not conducting rapid HIV testing at the time of the survey indicated they planned to implement it in 2008.

### **Implementation of Rapid HIV Testing**

Rapid HIV testing is broadly used by health departments as evidenced by the fact that survey respondents reported a total of 3,371 unique sites operated by 1,439 agencies that provide rapid HIV testing. Across the 47 health departments that responded to the items that examined the number of sites and agencies supported to provide rapid HIV testing, the median number of sites was 25 (Range 3 to 718) and the median number of agencies was 18 (Range 2 to 316).

Health departments that had implemented rapid HIV testing at the time of the survey were also asked to report on the settings and venues in which they support rapid HIV testing. These findings are presented in Table 1.

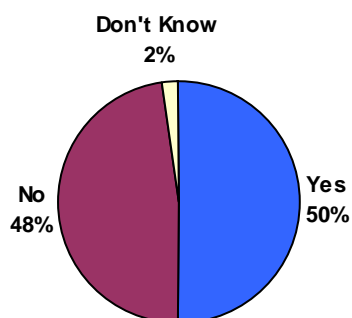
Table 1: "In what venues or settings does the health department currently (2007) support rapid HIV testing?" (N=47)	Percent responding
Outreach sites (N=45)	95.7%
Community-based organizations/AIDS service organizations (CBO/ASO) (N=44)	93.6%
HIV test sites (N=44)	93.6%
Local health departments (N=38)	80.9%
STD clinics (N=35)	74.5%
Substance abuse treatment centers (N=31)	66.0%
Partner counseling and referral services (PCRS) programs (N=29)	61.7%
Corrections (N=28)	59.6%
Community health clinics (N=25)	53.2%
Family planning clinics (N=21)	44.7%
TB clinics (N=16)	34.0%
Colleges (N=16)	34.0%
Primary care clinics (N=15)	31.9%
Hospital emergency departments (N=15)	31.9%
Prenatal/obstetrical clinics (N=11)	23.4%
Labor and delivery settings (N=11)	23.4%
Urgent care clinics (N=10)	21.3%
Other (e.g., churches, mobile units, migrant camps, shelters, soup kitchens, infectious disease clinics) (N=8)	17.0%

With regard to outreach venues, health departments were asked to describe the specific settings in which rapid HIV testing is used. These findings are presented in Table 2.

Table 2: "In which outreach and/or field venues is rapid HIV testing used?" (N=45)	Percent responding
Mobile van (N=33)	73.3%
Homeless shelters (N=28)	62.2%
Street outreach (N=25)	55.6%
Partner services field investigation (N=24)	53.3%
Churches (N=21)	46.7%
Bars (N=20)	44.4%
Bathhouses (N=16)	35.6%
Parks (N=15)	33.3%
Drug selling sites (N=12)	26.7%
Beauty shop/barbershops (N=5)	11.1%
House parties (N=3)	6.7%
Other outreach settings (e.g., events, work release facilities, substance abuse facilities, store fronts, detention centers) (N=10)	22.2%

With the release of the CDC's *Recommendations for HIV Testing of Adults, Adolescents and Pregnant Women in Health Care Settings* (2006), there has been increased interest in, and attention to, implementation of HIV testing in clinical settings. Health departments were asked whether they supported routine HIV testing<sup>2</sup> in health care settings. The responses to this item are presented in Figure 2.

Figure 2. Percent of Health Departments Supporting Routine HIV Testing in Health Care Settings (N=46)



Of the 23 health departments that responded in the affirmative to supporting routine HIV testing in health care settings, 22 (95.7percent) reported using rapid HIV testing in conjunction with these programs. The specific health care settings in which rapid HIV tests were used are presented in Table 3.

<sup>2</sup> Routine testing was defined as "voluntary HIV testing performed for all patients in a population unless the patient declines HIV testing."

Table 3: Health care settings in which rapid HIV testing is used in conjunction with routine HIV testing.	Percent responding
STD clinics (N=15)	68.2%
Community health centers (N=12)	54.6%
Family planning clinics (N=9)	40.9%
Correctional facilities (N=9)	40.9%
Primary care clinics (N=8)	36.4%
Substance abuse treatment centers (N=7)	31.8%
TB clinics (N=7)	31.8%
Hospital emergency departments (N=7)	31.8%
Labor and delivery settings (N=6)	21.3%
Perinatal/obstetrical clinics (N=4)	18.2%
Urgent care clinics (N=3)	13.6%
Hospital inpatient settings (N=2)	9.1%

### **Volume of HIV Testing**

Survey respondents were asked to report the number of conventional and rapid HIV tests conducted jurisdiction-wide during 2006 and to provide estimates for 2007 and 2008. In addition, health departments were asked to provide this information by specimen type, wherever feasible. These data are presented in Table 4. A total of 38 of the 51 (74.5 percent) health departments that responded to this survey provided information about volume of HIV testing for all three years examined.

Tests and Specimen Type	2006 (Actual) (N=39)	2007 (Estimated) (N=38)	2008 (Estimated) (N=38)
Standard laboratory tests using venipuncture or dried blood spot	508,095	499,433	474,489
Standard laboratory tests using oral fluid	142,587	139,784	149,175
Standard laboratory tests but specimen type cannot be determined	179,207	87,050	73,278
<i>Sub-Total Conventional Tests</i>	<i>829,889</i>	<i>726,267</i>	<i>696,942</i>
Rapid HIV tests conducted using fingerstick or venipuncture	138,527	207,419	356,194
Rapid HIV tests conducted using oral fluid	128,788	112,394	154,312
Rapid HIV tests but specimen type cannot be determined	337,552	358,102	548,130
<i>Sub-Total Rapid Tests</i>	<i>604,867</i>	<i>677,915</i>	<i>1,058,636</i>
<b>Total number of HIV tests conducted by health department supported programs (regardless of type of test or specimen)</b>	<b>1,678,952</b>	<b>1,633,485</b>	<b>2,093,339</b>

*\*\* Note: The total number of HIV tests conducted does not match the total number of tests by test and specimen type as only 31 of the 38 jurisdictions could provide information on test volume according to test and specimen type.*

**HIV Test Volume, 2006.** Thirty-nine (39) health departments reported a total of 1,678,953 HIV tests conducted in 2006 (Median 24,000; Range 2,570-297,698). Thirty-one (31) jurisdictions were able to provide data by specimen type, reflecting 1,434,756 (85.5 percent) of all HIV tests conducted in 2006. Of these, 829,889 (57.8 percent) were conventional HIV tests while 604,867 (42.2 percent) were rapid HIV tests.

Of all of the conventional HIV tests conducted in 2006, 142,587 (17.2 percent) were conducted on oral specimens and 508,095 (61.2 percent) were conducted on venous samples or dried blood spots (DBS). The specimen type could not be determined for 172,207 (21.6 percent) of all the conventional HIV tests conducted in 2006.

Of all of the rapid HIV tests conducted in 2006, 138,527 (22.9 percent) were conducted on fingerstick whole blood or venous samples and 128,788 (21.3 percent) were conducted on oral specimens. The specimen type could not be determined for 337,552 (55.8 percent) of all of the rapid HIV tests conducted in 2006.

HIV Test Volume, 2007 (Estimated). Thirty-eight (38) health departments estimated a total of 1,633,485 HIV tests would be conducted by the end of 2007 (Median 26,058; Range 780 – 334,275). Thirty-one (31) jurisdictions were able to provide data by specimen type, reflecting 1,404,182 (86.0 percent) of all HIV tests projected to be conducted in 2007. Of these, 726,267 (51.7 percent) are expected to be conventional HIV tests, while 677,915 (48.3 percent) are expected to be rapid HIV tests.

Of all of the conventional HIV tests that will be conducted in 2007, 499,433 (68.7 percent) will be conducted on venous samples or DBS and 139,784 (19.3 percent) will be performed with oral specimens. The specimen type could not be determined for 87,050 (12.0 percent) of all of the conventional HIV tests expected in 2007.

Of all of the rapid HIV tests to be conducted in 2007, health departments expected that 207,419 (30.6 percent) would be conducted on fingerstick whole blood or venous samples and 112,394 (16.6 percent) would be conducted on oral samples. Health departments were unable to determine the specimen type for 358,102 (52.8 percent) of all rapid HIV tests projected for 2007.

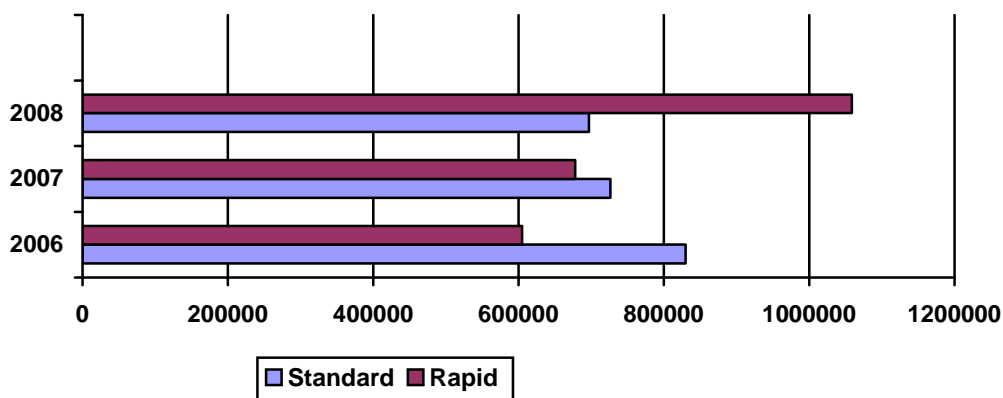
HIV Test Volume, 2008 (Estimated). Thirty-eight (38) health departments estimated a total of 2,093,339 HIV tests would be conducted in 2008 (Median 35,002; Range 800 – 358,100). Thirty-one (31) jurisdictions were able to provide data by specimen type, reflecting 1,755,578 (84.8 percent) of all HIV tests projected for 2008. Of these, 696,942 (39.7 percent) are projected to be conventional HIV tests while 1,058,636 (60.3 percent) are expected to be rapid HIV tests.

Of all of the conventional HIV tests that will be conducted in 2008, 474,489 (68.1 percent) are expected to be conducted on venous samples or DBS and 149,175 (21.4 percent) will be conducted on oral specimens. The specimen type could not be determined for 73,278 (10.5 percent) of all of the conventional HIV tests to be conducted in 2008.

Of all of the rapid HIV tests to be conducted in 2008, health departments expected that 356,194 (33.7 percent) would be conducted on fingerstick whole blood or venous samples and 112,394 (14.6 percent) would be conducted on oral samples. Health departments were unable to determine the specimen type for 548,130 (51.8 percent) of all rapid HIV tests projected for 2008.

Between 2006 and 2007, there was a projected decrease of 2.3 percent in overall HIV testing volume (Figure 3). Between 2007 and 2008, health departments projected a 28.2 percent projected increase in HIV test volume. Health departments receiving funding under CDC Program Announcement 07-768 (*Expanded and Integrated Human Immunodeficiency Virus (HIV) Testing for Populations Disproportionately Affected by HIV, Primarily African Americans*) tended to project larger increases to overall HIV test volume compared with health departments that did not receive PA 07-768 funding. Figure 3 also illustrates the increasing prominence of rapid HIV test technologies. Health departments expect that 51.8 percent of all HIV tests conducted in 2008 will be rapid, compared with 42.2 percent in 2006.

Figure 3: Number of HIV Tests, by HIV Test Type, by Year (2006-2008)

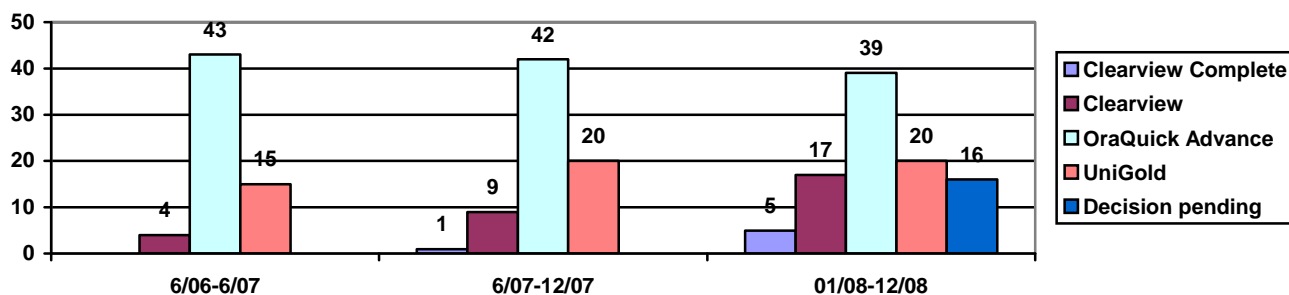


Only two health departments reported that they anticipated a decrease in the number of rapid HIV tests performed in 2008 compared with 2007: Missouri and Indiana. Indiana offered specific reasons for the anticipated decrease in the number of rapid HIV tests conducted, citing the end of the CDC bulk purchase and reductions in federal funding.

### **Selection and Use of Specific Rapid HIV Tests**

Health departments were asked to report which specific rapid HIV tests they were using during three time periods: June 2006 – July 2007, July 2007 – December 2007 (projected) and January 2008 – December 2008 (projected). Findings are presented in Figure 4.

Figure 4: Number of Health Departments Using Specific Rapid HIV Tests in Conjunction with Health Department Supported HIV Testing Programs (N=44)



Between June 2006 and June 2007, CDC implemented a bulk purchase of rapid HIV tests (specifically OraQuick Advance®) and distributed test devices to health departments. Health departments were asked to report on the specific rapid HIV tests used during this time in conjunction with health department supported HIV testing programs. Of 44 health departments responding to this question, 43 (97.7 percent) reporting using OraQuick Advance®; 15 (34.1 percent) reported using UniGold™; and four (9.1 percent) reported using Clearview®. None of the responding health departments reported using Clearview® Complete, Multi-Spot™ or Reveal®. One health department (Wyoming) reported using UniGold™ exclusively while 14 health departments reported using UniGold™ and OraQuick Advance® and two health departments indicated using Clearview® and OraQuick Advance®. Two health departments (Louisiana and Los Angeles County) reported using tests from three manufacturers (OraQuick Advance®, UniGold™ and Clearview®).

One health department (Los Angeles County) indicated that the use of rapid HIV tests from multiple manufacturers was part of a research study. Another health department (San Francisco) indicated that they did not know whether the use of multiple rapid HIV tests from different manufacturers was part of a research study.

The CDC bulk purchase and distribution of rapid HIV tests ended in July 2007. Health departments were asked to report on the specific rapid HIV tests used since the end of the bulk purchase and the time of the survey administration (November and December 2007). Of 44 health departments responding to this question, 42 (95.5 percent) reporting using OraQuick Advance®; 20 (45.5 percent) reported using UniGold™; nine (20.5 percent) reported using Clearview® and one (2.3 percent) reported using Clearview® Complete. None of the responding health departments reported using Multi-Spot™ or Reveal®.

Two health departments (Wyoming and Kansas) reported using UniGold™ exclusively while 16 health departments reported using UniGold™ and OraQuick Advance®; seven health departments indicated using Clearview® and OraQuick Advance®; and one health department (Oklahoma) reported using OraQuick Advance® and Clearview® Complete. Two health departments (Louisiana and Los Angeles County) reported using tests from three manufacturers (OraQuick Advance®, UniGold™ and Clearview®).

Three health departments (Los Angeles County, San Francisco and North Carolina) indicated that the use of rapid HIV tests from multiple manufacturers was part of a research study.

Health departments were asked to indicate which rapid HIV tests they planned to use in 2008. Responses to this item, by jurisdiction, are available in Appendix B. Forty-four health departments responded to this question. Of these, 39 (88.6 percent) reported planning to use OraQuick Advance®; 20 (45.5 percent) plan to use UniGold™; 17 (38.6 percent) plan to use Clearview®; and five (11.4 percent) plan to use Clearview® Complete. None of the responding health departments reported plans to use Multi-Spot™ or Reveal®. However, 16 (36.4 percent) indicated that, at the time of the survey, the decision about which test(s) to use in 2008 was “under consideration, decision pending.” One health department indicated “don’t know” in response to this question.

Sixteen (36.4 percent) of the 44 health departments responded to the question about which rapid test(s) they plan to use indicated an intent to use only one rapid test in 2008 in conjunction with health department supported HIV testing programs. Of these, 15 (93.8 percent) reported that they plan to use OraQuick Advance® and one plans to use UniGold™. However, eight of the sixteen also indicated that the rapid HIV test(s) that would be used in 2008 were still under consideration, with a decision pending at the time of the survey.

Ten (22.7 percent) of the 44 health departments reported that they plan to use two tests in 2008. Six health departments planned to use OraQuick and UniGold™ and four reported they planned to use Clearview® and OraQuick Advance®. One of these health departments also indicated that their final plans for 2008 were still under consideration, with a decision pending at the time of the survey.

Eleven (25.0 percent) health departments reported that they plan to use three different tests in 2008. Ten health departments reported that they planned to use Clearview®, Clearview® Complete and OraQuick Advance®. One health department reported that it planned to use Clearview® Complete, OraQuick Advance® and UniGold™. Four of these eleven health departments also indicated that their final plans for 2008 were still under consideration, with a decision pending at the time of the survey.

Three health departments reported that they planned to use all of the four waived rapid HIV tests in 2008 (i.e., Clearview®, Clearview® Complete, OraQuick Advance® and UniGold™). Finally, four health departments indicated that their plans for 2008 were under consideration at the time of the survey with a decision pending or that they did not know what rapid HIV tests they expected to use in 2008.

Health departments were asked to identify the factors that were used to determine which rapid HIV test(s) would be used in 2008. Findings are presented in Table 5 and suggest that health departments consider a number of criteria in making decisions about which rapid HIV tests to use.

Table 5: Factors Determining Which Rapid HIV Test(s) Will Be Used in 2008 (N=44)	Percent responding
Price (N=35)	79.5%
Length of shelf life (tests) (N=33)	75.0%
Ease of specimen collection (N=30)	68.2%
Sensitivity (N=29)	65.9%
Ease of integration into service/clinic flow (N=29)	65.9%
Specificity (N=28)	63.6%
Approved for oral specimens (N=24)	54.5%
Length of shelf life (controls) (N=24)	54.5%
Run time (N=23)	52.3%
Ease of reading results (N=22)	50.0%
Operating temperatures (N=18)	40.9%
Approved for HIV-2 (N=16)	36.4%
Read window (N=15)	34.1%
Storage temperature (N=12)	27.3%
Other (e.g., cost, choice for providers, existing contract, decision pending, lab will decide, user survey) (N=7)	15.9%

Price and shelf life of test devices were cited by a substantial majority of health departments followed by ease of specimen collection, sensitivity, ease of integration into services and/or clinic flow and specificity. A slim majority cited approved for oral specimens, control shelf life and run time as factors used in deciding which rapid HIV tests would be deployed in 2008 in conjunction with health department supported HIV testing programs.

Health departments were asked to rank the three most important factors that determined which rapid HIV test(s) they would use in 2008. The findings are presented in Table 6.

Table 6: Ranking of Factors Used in Selecting Rapid HIV Test(s) in 2008 (N=44)	Top 3 factors (number and percent)	Most important factor (number and percent)
Price	31 (70.5%)	17 (38.6%)
Length of shelf life (tests)	17 (38.6%)	4 (9.1%)
Approved for oral specimens	16 (36.4%)	5 (11.4%)
Sensitivity	10 (22.7%)	7 (15.9%)
Ease of specimen collection	10 (22.7%)	2 (4.6%)
Ease of performing test	7 (15.9%)	1 (2.3%)
Specificity	7 (15.9%)	0
Run time	5 (11.4%)	2 (4.6%)
Ease of integration into service/clinic flow	4 (9.1%)	2 (4.6%)
Operating temperature	3 (6.8%)	1 (2.3%)
Length of shelf life (controls)	3 (6.8%)	0
Approved for HIV-2	3 (6.8%)	0
Ease of reading results	2 (4.6%)	0
Read window	2 (4.6%)	0
Storage temperature	1 (2.3%)	0
Other (e.g., meeting laboratory requirements, existing contracts, established name)	3 (6.8%)	2 (4.6%)

By a substantial margin, price appears to be the single most important determining factor used in selected rapid HIV tests with 70.5 percent of respondents citing it as one of the three most important factors and 38.6 percent citing it as the most important determining factor.

Rapid HIV test shelf life was among the three most important factors for nearly four of ten respondents (38.6 percent), followed by approved for oral specimens (36.4 percent), sensitivity (22.7 percent) and ease of specimen collection (22.7 percent). Sensitivity was identified as the most important factor by 15.9 percent of respondents, while approved for oral specimens was identified as the most important factor by 11.4 percent of respondents and rapid HIV test shelf life was cited as the most important factor by 9.1 percent of health departments.

### **Procurement**

Procurement of rapid HIV tests, including the mechanisms used by health departments to purchase rapid HIV tests, was examined. Health departments were asked to indicate the approximate number of rapid HIV tests purchased through various procurement mechanisms during 2007 and to estimate the number of rapid HIV tests they would purchase through various procurement mechanisms in 2008. These findings are presented in Table 7.

Table 7: Number of Rapid HIV Tests Purchased by Procurement Mechanism	2007 (N=45)		2008 (Estimated) (N=45)	
	Number of health departments	Number of rapid HIV tests	Number of health departments	Number of rapid HIV tests
Directly by the health department HIV prevention program	37 (82%)	772,495	40 (89%)	1,120,300
Through another state/local department or organizational unit within the health department (e.g., laboratory)	9 (20%)	65,620	8 (18%)	79,860
Through an intermediary entity (e.g., hospital, CBO/ASO)	6 (13%)	122,863	10 (22%)	190,598
340 B program	1 (2%)	200	1 (2%)	1,000
Other (e.g., another state agency)	6 (13%)	116,250	3 (7%)	162,100

*Note: Percentage of health departments reporting particular procurement mechanisms exceeds 100 percent as multiple responses were accepted.*

In 2007, health departments purchased 1,077,428 rapid HIV tests through one or more procurement mechanisms. Among the six health departments that referenced “other” as a procurement mechanism, one indicated that rapid HIV tests were purchased through another state agency. The remaining five health departments that reported “other” in response to this question indicated having received rapid HIV tests at no cost through the CDC or the state health department.

In 2008, health departments plan to purchase 1,553,858 rapid HIV tests through one or more procurement mechanisms. The three health departments that reported “other” in

response to this question indicated that they expected to receive rapid HIV tests at no cost through the state health department, other state agency or through donation.

Health departments were asked to describe the procurement mechanism(s) that they would use in 2008 to purchase rapid HIV tests. Findings are presented in Table 8.

Table 8: Procurement Process for Purchasing Rapid HIV Tests in 2008 (N=46)	Percent responding
Health department procurement process (e.g., bid) (N=18)	39.1%
HIV prevention program negotiates directly with companies and purchases through health department procurement process (N=24)	52.2%
HIV prevention program negotiates directly with companies and purchases outside of health department procurement process (N=4)	8.7%
Another state/local department or organizational unit within the health department purchases tests (N=7)	15.2%
Resources directed to an intermediary agency (N=8)	17.4%
Funding is provided to grantees and other local providers to purchase tests (N=9)	19.6%
340 B Program	0.0%
Other (N=3)	6.5%

*Note: Responses do not total 100 percent as multiple responses were accepted.*

All eighteen health departments that reported “health department procurement process” in response to this question also provided a description of their procurement process. Thirteen of these health departments indicated that procurement involved a competitive bidding process. The remaining five health departments did not provide sufficiently descriptive responses to discern the nature of their health department procurement process.

## **Performance**

Health departments were asked to identify any clusters of false positive rapid HIV test results experienced since June 2005. Twelve health departments reported experiencing one or more clusters<sup>3</sup> of false positives. As presented in Table 9, eleven of these health departments were able to provide some specific data regarding 20 total clusters of false positive results, including the time period during which the clusters occurred as well as the total number of false positive, true positive and negative test results. All twenty clusters involved the OraQuick Advance® rapid HIV test.

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<sup>3</sup> A “cluster” is defined as an unexpected increase in false-positive rapid HIV test results within a defined time period.

Table 9: False-Positive Clusters of Rapid HIV Tests since June 2005, by Health Department				
Jurisdiction	Time period	Total false positive tests	Total true positive tests	Total negative tests
Delaware	04/22/2007-06/29/2007	15	16	2,623
Delaware	12/19/2005-07/11/2007	20	24	5,202
North Carolina	10/06/2007-10/06/2007	2	11	1505
North Carolina	02/26/2007-02/26/2007	4	5	166
North Carolina	09/27/2006-09/27/2006	2	10	642
New Jersey	01/15/2007-04/15/2007	6	1	367
New Jersey	08/01/2006-08/31/2006	17	1	340
New Jersey	06/01/2007-06/30/2007	4	14	186
Louisiana	07/15/2006-12/31/2006	57	145	7,518
Oregon	10/09/2006-06/27/2007	5	4	306
Oregon	08/08/2007-11/16/2007	2	2	116
Oregon	09/13/2006-11/15/2006	3	0	65
Michigan	10/03/2005-10/31/2005	10	0	1,720
Michigan	08/10/2005-08/30/2005	7	0	734
Los Angeles	08/01/2005-11/30/2005	12	10	1,464
Ohio	10/03/2006-10/26/2006	11	37	3,642
Wisconsin	06/01/2007-09/30/2007	11	36	3,440
Indiana	12/15/2005-06/15/2006	40	0	40
San Francisco	07/01/2005-12/31/2005	48	130	542
San Francisco	08/01/2007-09/30/2007	16	48	2,039

All twelve health departments that experienced one or more clusters of false positives reported their findings from investigations into the possible causes of the false positive results. The components of the health department investigations are presented in Table 10.

Table 10: Components of Health Department Investigations of False Positive Rapid HIV Test Clusters (N=12)	Percent responding
Review of quality control practices (N=12)	100%
Discussion of possible causative factors with test operators (N=12)	100%
Review of quality control documentation (e.g., temperature logs, testing logs) (N=11)	91.7%
Observation of test practices (N=11)	91.7%
Worked in collaboration with manufacturer representatives (N=11)	91.7%
Other (e.g., photographed read lines, provided data to manufacturer, provided specimen collection instruction to test operators, training) (N=4)	33.3%

Eleven of the twelve health departments experiencing one or more clusters of false-positive rapid HIV tests indicated that they notified the involved rapid HIV test manufacturer about the cluster(s) of false positive.

As a result of these investigations, a number of factors were thought to play a role in the clusters of false positive rapid HIV test results. Five health departments (41.7 percent) indicated that the false positive clusters might be attributed to over-collection of the specimen. Three health departments (25.0 percent) indicated that out-of-range storage temperatures might have played a role in the false positive clusters. Only one health department (8.3 percent) reported that false positive clusters might be attributable to out-of-range operating temperatures. One health department also indicated that they suspected a test lot nearing expiration was the cause of their false positive clusters. None of the health departments attributed any of the false positive clusters to a mix up of patient specimens or to a failure to read test results in the correct time frame. Five health departments (41.7 percent) reported that they were unable to identify the factors or reasons for the cluster(s) of false positives.

### **Use of Combinations of Rapid Tests at Individual Sites**

CDC and the Association of Public Health Laboratories (APHL) have begun development of guidelines for using combinations of rapid HIV tests to aid in the diagnosis of HIV infection at the point-of care (i.e., multi-test algorithms). NASTAD is collaborating with CDC and APHL in this effort. Information about how various rapid HIV tests are used in combination as well as the performance of such combinations is needed to better inform development of the guidelines. To this end, the use by health departments of multiple rapid HIV tests in combination was examined. Four health departments<sup>4</sup> reported that one or more sites routinely run one or more additional rapid HIV test(s) in a sequential algorithm<sup>5</sup> to retest any initial reactive rapid HIV test results for clients during the same visit. Two health departments (50.0 percent) reported that use of multiple rapid HIV tests in a sequential algorithm is a health department standard of practice, and two health departments (50.0 percent) reported that use of multiple rapid HIV tests in a sequential algorithm has been voluntarily adopted by one or more individual HIV test site as a standard practice. Only one health department (Los Angeles County) reported that the use of multiple rapid HIV tests in a sequential algorithm was part of a research study. The four health departments provided detailed information regarding their use of multiple rapid HIV tests in a sequential algorithm. This information is presented in Table 11.

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<sup>4</sup> Health departments reporting using multiple rapid tests in a sequential algorithm include Los Angeles County, Montana, New York City and San Francisco.

<sup>5</sup> Sequential means that only one rapid test is used as the screening test, i.e., the first step of the test algorithm.

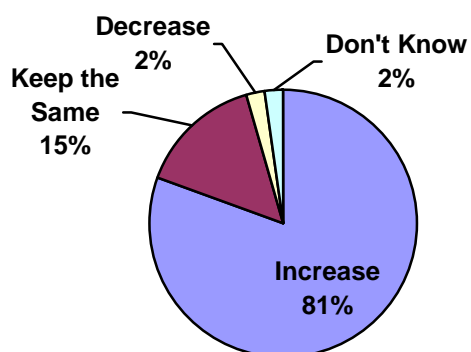
Jurisdiction	Number of sites using sequential algorithm	Number of sequential algorithms	First test	Second test	Third test
Los Angeles County	3	1	OraQuick Advance (Oral)	Clearview/StatPak (Venipuncture)	UniGold (Venipuncture)
Montana	10	1	OraQuick Advance (Oral)	OraQuick Advance (Fingerstick)	NA
New York City	20	1	OraQuick Advance (Oral)	OraQuick Advance (Fingerstick)	NA
San Francisco	5	2	OraQuick Advance (Oral) OraQuick Advance (or Fingerstick)	Clear view/StatPak (Venipuncture) Clear view/StatPak (Venipuncture)	UniGold (Venipuncture) UniGold (Venipuncture)

One health department (South Carolina) reported using two or more rapid HIV tests in a parallel<sup>6</sup> algorithm on a routine basis. The health department, however, did not provide information regarding the specific tests used in the algorithm.

### **Future Plans for Rapid HIV Testing**

The final section of the survey addressed health department plans for rapid HIV testing programs in 2008. Specifically, health departments were asked to indicate whether they planned to increase, decrease or keep the same number of sites using rapid HIV testing in 2008. As illustrated in Figure 5, more than eight of ten health departments plan to increase the number of sites that will be using rapid HIV testing.

*Figure 5: Responses to “In 2008, will you be increasing, decreasing or keeping the same number of sites using rapid HIV testing?” (N=46)*



<sup>6</sup> Parallel means that at least two rapid HIV tests are used together, i.e., at least two screening tests.

One health department indicated that it would be decreasing the number of sites conducting rapid HIV testing in 2008. This jurisdiction reported that the planned decrease in the number of sites offering rapid HIV testing is attributed to a lack of resources. One health department reported “don’t know” to the question addressing plans for increasing/decreasing the number of rapid HIV testing sites in 2008.

Health departments planning to expand the number of sites providing rapid HIV testing in 2008 were asked to indicate the types of settings and venues in which rapid HIV testing would be expanded. These findings are presented in Table 12.

Table 12: Settings and Venues for Planned Expansion of Rapid HIV Testing in 2008	Percent responding
Outreach venues (N=29)	78.4%
CBO/ASO (on-site) (N=25)	67.6%
HIV testing sites (N=25)	67.6%
Substance abuse treatment centers (N=22)	59.5%
Local health departments (N=22)	59.5%
Community health clinics (N=22)	59.5%
Hospital emergency departments (N=22)	59.5%
Correctional facilities (N=21)	56.8%
STD clinics (N=21)	56.8%
PCRS programs (N=20)	54.1%
Primary care clinics (N=15)	40.5%
Family planning clinics (N=12)	32.4%
Urgent care clinics (N=11)	29.7%
Colleges (N=11)	29.7%
TB clinics (N=10)	27.0%
Labor and delivery settings (N=8)	21.6%
Prenatal/obstetrical clinics (N=5)	13.5%

Health departments were also asked to report the approximate number of additional sites where they would be supporting rapid HIV testing in 2008. The 37 health departments reporting that they would be increasing the number of sites offering rapid HIV testing reported that they expected to add approximately 562 new rapid HIV test sites (Range 2 – 100; Median 10).

### **Technical Assistance Needs**

Health department technical assistance needs that cannot be addressed by the health departments themselves are presented in Table 13.

Table 13: Rapid HIV Testing Technical Assistance Needs That Cannot Be Addressed by the Health Department (N=46)	Percent responding
Adopting multi-test algorithms (N=21)	45.7%
Evaluating the cost-effectiveness of rapid HIV testing (N=20)	43.5%
Evaluating the impact of rapid HIV testing (N=17)	37.0%
Validating rapid HIV tests from various manufacturers (N=12)	26.1%
Identifying appropriate venues/populations to implement rapid HIV testing (N=7)	15.2%
Laboratory training for local providers (N=4)	8.7%
Rapid HIV test device training (N=4)	8.7%
Providing rapid HIV testing in specific venues or settings (N=4)	8.7%
Laboratory training for health department staff (N=1)	2.2%
Counselor training (N=1)	2.2%
Other (e.g., routine rapid testing, funding, quality assurance, on-street testing, phlebotomy certification, multi-test algorithms) (N=7)	15.2%

The findings indicate relatively limited need for basic training on the technical aspects of rapid HIV testing. Health departments report a greater need for assistance and support in evaluating the effectiveness and efficiency of rapid HIV testing to inform policy and program planning decisions.

## **DISCUSSION**

### **Uptake of Rapid HIV Testing**

A large majority (94 percent) of health departments indicate that they have implemented rapid HIV testing. This represents a significant increase in the eighteen months since NASTAD's initial survey of health departments in which 81 percent of health departments indicated having implemented rapid HIV testing. By the end of 2008, it is likely that nearly every state and directly-funded city health department will have implemented rapid HIV testing.

Health departments projected a relatively large increase (28.2 percent) in the number of HIV tests to be conducted in 2008. Data from the current survey, combined with data from the 2006 survey, indicates a downward trend in the total volume of HIV tests conducted by health departments from 1,803,707 in 2005 to 1,633,485 in 2007. Health departments receiving funding under PA 07-768 tended to project larger increases to overall HIV test volume compared with other health departments, and, therefore, the projected increase may likely be due, in part, to increased federal funding.

Data from this survey combined with data from the 2006 survey indicates that rapid HIV testing accounts for an increasing percentage of all HIV tests conducted by health departments, from approximately 25 percent of all HIV tests conducted in 2005 to nearly 51 percent in 2008. This trend is likely due to multiple factors including health

department capacity to support rapid HIV testing, decreasing cost of rapid HIV tests, as well as increased funding for expansion of HIV testing, particularly in high volume clinical settings.

A large majority of health departments plan to expand the number of sites that offer rapid HIV testing in 2008. The sites where planned expansion will occur represent a wide range of community-based, outreach and clinical venues. Given the influx of federal funding to support expansion of HIV testing in clinical settings, it is not surprising that nearly six in ten health departments responding to this survey expect to expand rapid HIV testing in one or more clinical settings in 2008, including community health clinics, hospital emergency departments, STD clinics and substance abuse treatment centers.

However, with continued reductions to federal funding in health department cooperative agreements and increasingly constrained state funding being reported by many health departments, it will be important to monitor the extent to which resource issues impact the adoption and expansion of HIV testing programs and, specifically, the uptake of rapid HIV testing. In particular, it will be important to closely examine the expansion of HIV testing for recipients of funding under PA 07-768, which emphasized implementation of HIV testing in clinical settings, to determine the extent to which projected increases in HIV testing is observed and to make adjustments to programmatic goals and expectations, as appropriate, at both the state/local and national levels. It will also be important to monitor the extent to which health department HIV testing portfolios are balanced with respect to HIV testing in community-based and clinical venues; and targeted versus screening approaches to ensure that health departments optimize yield and effectively use public resources. It will also be essential to monitor the balance between HIV testing efforts and other non-diagnostic prevention strategies within health department HIV prevention programs.

### **Settings and Venues**

Rapid HIV testing is supported in a wide variety of venues, including clinical settings which have received increased attention since the release of CDC's *Recommendations for HIV Testing in Health Care Settings* in September 2006. When compared with findings from the 2006 survey, health departments have expanded rapid HIV testing in several key venues and settings. Three-quarters of health departments are using rapid HIV testing in STD clinics compared with 67 percent in 2006; 60 percent are using rapid HIV testing in correctional settings compared with 47 percent in 2006; and approximately 32 percent of health departments are using rapid HIV testing in emergency departments compared with 19 percent in 2006. Rapid HIV testing is also used by approximately 62 percent of health departments in conjunction with partner counseling and referral services, compared with 37 percent in 2006.

Expansion of rapid HIV testing is also evident in community-based settings and venues. The current survey indicates that approximately 96 percent of health departments use rapid HIV testing in conjunction with outreach compared with 81 percent in 2006. Rapid

HIV testing provided through mobile van outreach was reported by approximately 73 percent of health departments in the current survey compared with 60 percent in 2006. Rapid HIV testing in homeless shelters was reported by 62 percent of health departments in the current survey, compared with 40 percent in 2006.

### **Rapid HIV Testing in the Context of Overall Testing Efforts**

While rapid HIV testing appears to be an increasingly prominent tool used in health department HIV testing efforts, it is important to highlight that conventional laboratory HIV testing continues to play an important role in these efforts, with nearly 700,000 such tests projected to be performed in 2008. For this reason, it is important for health departments to continue to maintain and enhance the capacity for laboratory-based HIV testing, including adoption of new laboratory-based testing algorithms currently under development by CDC and APHL.

Data gathered through this survey indicates that oral fluid HIV testing continues to be an important necessity. While several health departments were unable to provide the specimen type for all conventional laboratory HIV tests conducted, respondents indicated that at least 150,000 conventional HIV tests will be conducted on oral fluid specimens in 2008, representing at least one in every five HIV tests conducted using conventional laboratory HIV test technology. It is also notable that health departments projected a slight increase (6.7 percent) in the number of conventional HIV tests that will be conducted on oral fluid in 2008.

In mid-2007, bioMérieux discontinued production of their HIV-1 serum and oral fluid Vironostika EIA platforms. In response to the lack of availability of an FDA-approved HIV oral fluid screening assay, APHL received approval from the Centers for Medicare and Medicaid Services (CMS) for a proposal to allow public health laboratories to perform a small scale validation study for use of the Bio-Rad HIV-1/2 plus O serum-based screening assay for testing oral fluid specimens. This proposal was accepted by CMS for use only as an emergency short-term measure. Therefore, it is essential that an oral fluid screening assay be developed and approved by the FDA to ensure the continued capacity of public health laboratories to provide oral fluid HIV testing and to ensure the sustainability of health department HIV testing programs.

Recently, health departments have reported a substantial increase in the cost of the oral fluid Western blot distributed by OraSure® Technologies. This is currently the only FDA-approved Western blot available for use with oral fluid. The potential impact of this cost increase has yet to be seen, but it is possible that many health departments will be forced to seek alternative means for confirmatory testing (e.g., validation of serum-based Western blots) or discontinue oral fluid HIV testing altogether.

## **Selection of Rapid HIV Tests**

Price was decidedly the single most important factor cited by health departments in determining which rapid HIV test(s) to use. Increased competition from multiple manufacturers of rapid HIV tests is expected to continue to drive down the cost of rapid HIV tests. At the same time, health departments will continue to deploy rapid HIV testing in a wide range of settings and for diverse populations. Health departments may increasingly seek to “match” HIV test features to venues, settings and populations in order to optimize HIV testing efforts. In this circumstance, factors other than price (e.g., ease of use, read time, operating temperature, specimen) may be paramount in decision-making regarding which rapid HIV test(s) are to be used. “Matching” of tests to venues and settings may, in part, explain the finding that many health departments indicated that they plan to use rapid HIV tests from two or more manufacturers in 2008. Only slightly more than one-third (36.4 percent) of the 44 health departments responding indicated plans to use a rapid HIV test from only one manufacturer. It will be important to monitor the features of each of the HIV rapid tests that facilitate and/or challenge use of rapid HIV tests in various settings in order to provide technical assistance to health departments and their grantees.

Shelf life also featured prominently among the factors considered by health departments in determining which rapid HIV tests would be used in 2008. Health department procurement processes sometimes necessitate purchases of a large number of rapid HIV tests at one time. Thus, maximizing shelf life of rapid HIV tests is essential. Anecdotal information suggests that some health departments rely on “soft money” (non-renewable or one-time resources) to purchase rapid HIV test kits, which also drives the need to make large purchases of tests at one time. In these jurisdictions, shelf life of rapid HIV test kits is a key concern.

The ability to test using oral fluid was also cited by health departments as an important factor considered in determining which rapid HIV test(s) would be used. The majority of health departments (88.6 percent) reported planning to use OraQuick Advance®, the only rapid HIV test approved for use on oral fluid. However, only one-third of health departments intend to use this product exclusively. This finding underscores that health departments need to be able to maintain flexibility with respect to the specific rapid HIV test technology adopted.

## **Procurement**

Health departments expect to increase by nearly 500,000 the number of rapid HIV tests they will purchase in 2008, compared with 2007. This is likely a reflection of increased federal funding for HIV testing coupled with decreasing price of rapid HIV tests. Most health departments utilize their health department procurement process to purchase rapid HIV tests, which generally takes the form of a competitive bidding process. Compared with 2007, more health departments appeared to provide funding to grantees or other intermediary agencies to purchase rapid HIV tests. Only one health department reported having been able to take advantage of 340 B pricing, although

health department grantees may be able to do so. This may explain, in part, the increase in the number of jurisdictions that are providing funding to intermediary agencies to purchase rapid HIV tests.

## **Performance**

Twelve health departments reported clusters of false positives over the past few years. These clusters occurred beginning in 2005 and occurred as late as November 2007, when this survey was administered. All clusters of false positives involved OraQuick Advance®, which was in relatively widespread use at the time of the survey. A number of factors were thought to play a role in the clusters of false positive rapid HIV test results, including over-collection of specimen, storage temperatures, operating temperatures and lot manufacture. While the survey did not specifically inquire as to what specimen types were involved in the clusters, anecdotal information provided by health departments indicated that a majority of the clusters may have involved oral fluid. The survey also did not inquire as to what procedural changes were made, if any, to rapid HIV testing programs. However, several health departments have reported having shifted primarily or entirely to whole blood specimens acquired via fingerstick as a result of the clusters of false positives. Health departments will need to continue to monitor performance of rapid HIV tests, particularly as they adopt rapid HIV tests from different manufacturers.

## **Use of Combinations of Rapid Tests**

Very few health departments report using a multi-test algorithm for rapid HIV testing. Of the four that reported using a multi-test sequential algorithm, only two reported using rapid HIV tests from different manufacturers. The other two reported using an algorithm involving one rapid HIV test from the same manufacturer (OraQuick Advance®) on two specimen types.

Guidelines to confirm HIV-1 infection currently require testing with Western blot (WB) or indirect immunofluorescence assay (IFA). These guidelines have been in place for more than two decades. Since this time, newer technologies that have greater sensitivity, are less costly and can be conducted at point-of-care by personnel with limited training have been developed and approved by the FDA. Use of multiple rapid tests for diagnostic purposes has been widely deployed in non-U.S. settings. Compared with the current WB/IFA confirmatory algorithm, combinations of rapid HIV tests for diagnostic purposes may help to identify infections earlier, reduce costs for testing and follow-up and increase the number of clients who learn their HIV test results and are linked with medical care, treatment, prevention and support services. Development of new national guidelines which address the application of rapid HIV tests in multi-test algorithms for use in diagnosing HIV infection are needed. Data to support recommendations of particular multi-test algorithms are needed to inform national guidelines. Such guidelines may stimulate health departments to consider adopting multi-test algorithms for diagnosing HIV infection using rapid technologies. At the same time, as more rapid HIV tests which are classified as CLIA-waived become

available and the prices of rapid HIV tests drop, more health departments may wish to explore adoption of multi-test algorithms as a means to increase the efficiency and effectiveness of HIV testing programs.

### **Technical Assistance Needs**

Of all health departments, 45.7 percent reported a need for technical assistance in adopting multi-test algorithms for point-of-care confirmation of HIV infection. This technical assistance need received the most frequent mention of all the technical assistance needs referenced on the survey questionnaire. This suggests an interest and willingness on the part of health departments to adopt multi-test algorithms to conduct confirmation at point-of-care. Thus, development of guidelines and associated training and technical assistance to support adoption of multi-test algorithms should be prioritized.

A large proportion of health departments identified a need for technical assistance and support in evaluating the cost-effectiveness of rapid HIV testing (43.5 percent) and in evaluating the impact of rapid HIV testing (37.0 percent). In our 2006 survey, a slim majority (51.2 percent) also indicated a need for assistance in evaluating the impact of rapid HIV testing and evaluating the cost-effectiveness of rapid HIV testing (44.2 percent). These findings suggest a continuing need among health departments to better understand, and perhaps defend, the relatively sizeable, ongoing investment in rapid HIV testing, particularly in comparison with conventional HIV testing. Such evaluation should be a priority area for support and technical assistance.

The survey findings indicate a very limited need for basic training and skills development on the technical aspects of rapid HIV testing, including device training, laboratory training and counselor training. Only four (8.7 percent) health departments reported a need for laboratory or test device training. In comparison, nearly 40 percent of health departments indicated a need for training on test devices in 2006 and 30 percent indicated a need for laboratory training. This suggests that health departments have rapidly built internal capacity for providing the necessary training and technical assistance on the technical aspects of HIV testing with rapid technologies.

### **LIMITATIONS**

There are several limitations to these findings. All data were self-reported and are subject to the knowledge and interpretation of the individual(s) who completed the survey. Several survey questions asked respondents to quantify HIV test volume, either in terms of the number of HIV tests conducted or the number of HIV test devices purchased. Several health departments were not able to provide these data, including some jurisdictions that are known to conduct relatively high volumes of HIV tests. One question asked health departments to quantify the number of HIV tests conducted by specimen types. Again, several health departments were not able to provide this information. Therefore, all survey questions which address the volume of HIV tests conducted or purchased under-represent the total volume of HIV tests.

Questions which asked health department to provide the number of HIV tests that will be conducted (for 2007 and 2008) and the number of tests to be purchased (for 2008) represent estimates only and, therefore, should be interpreted with caution as the estimates can be influenced by multiple factors such as funding and implementation issues.

This survey asked health departments to provide retrospective data regarding HIV test performance. This proved challenging for health departments, particularly where data were not compiled and managed in electronic file formats. Two health departments each provided two separate sets of data which were not entirely consistent and required additional investigation to reconcile data.

## APPENDIX A: Survey



### HIV Rapid Testing Survey – November 2007

This survey is being conducted by NASTAD to continue monitoring health department efforts to implement and support rapid HIV testing. It is a follow-up to a survey that NASTAD conducted in May of 2006. This assessment expands on our previous survey by examining issues associated with adoption of rapid tests from various manufacturers, performance of rapid HIV tests and use of multi-test algorithms. The findings from this survey will contribute to the development and prioritization of technical assistance activities, guide education and advocacy efforts and will also contribute to the development of guidelines for multi-test rapid HIV test algorithms. Please complete and return this questionnaire as soon as possible, but no later than **Wednesday, November 21, 2007**.

Name:

Jurisdiction:

Phone:

E-mail:

1. Does the health department currently support HIV rapid testing? *Note: "support" refers to HIV testing efforts which receive funding or other support (such as provision of test devices), from the health department.*  Yes  No

a. If "No" to Question 1, please check the reason(s) why the health department does not currently support rapid HIV testing (*Check all that apply*):

Statutory/regulatory barriers

Please describe barriers:

Lack of resources

Lack of health department infrastructure

Lack of local provider capacity

No clear programmatic use

Rapid testing is supported by other state agencies

Rapid testing is supported by the CDC through directly-funded CBOs/ASOs

Rapid testing is supported by other federal agencies (please list which federal agencies):

Other (please describe):

b. If "No" to Question 1, does the health department plan to support a rapid test program in 2008?  Yes  No

## IMPLEMENTATION

The questions in this section address rapid HIV testing as it is currently implemented in the context of health department supported HIV prevention efforts.

2. In what venues or settings does the health department currently support rapid HIV testing? (*Check all that apply*)

- |  |   |
|--|---|
| <input type="checkbox"/> PCRS program                      | <input type="checkbox"/> Prenatal/obstetrical clinics   |
| <input type="checkbox"/> CBOs/ASOs ( <i>on-site only</i> ) | <input type="checkbox"/> Labor and delivery facilities  |
| <input type="checkbox"/> Substance abuse treatment         | <input type="checkbox"/> Community health centers       |
| <input type="checkbox"/> HIV testing sites                 | <input type="checkbox"/> Family planning clinics        |
| <input type="checkbox"/> Outreach venues                   | <input type="checkbox"/> TB clinics                     |
| <input type="checkbox"/> Local health departments          | <input type="checkbox"/> Colleges                       |
| <input type="checkbox"/> Correctional facilities           | <input type="checkbox"/> Hospital emergency departments |
| <input type="checkbox"/> STD clinics                       | <input type="checkbox"/> Primary care clinics           |
| <input type="checkbox"/> Urgent care clinics               | <input type="checkbox"/> Other (please describe):       |

3. Does the health department support rapid HIV testing in conjunction with outreach and/or field-based activities?  Yes  No  Don't know

- a. If "Yes" to question 3, please indicate in which of the following outreach/field venues in which rapid HIV testing is used (*Check all that apply*).

- |  |  |
|--|--|
| <input type="checkbox"/> Bars                                    | <input type="checkbox"/> House parties   |
| <input type="checkbox"/> Bathhouses                              | <input type="checkbox"/> Parks   |
| <input type="checkbox"/> Beauty shop/barbershops                 | <input type="checkbox"/> Homeless shelters                                     |
| <input type="checkbox"/> Mobile van                              | <input type="checkbox"/> Street outreach                                       |
| <input type="checkbox"/> Drug selling sites (crack houses, etc.) | <input type="checkbox"/> Partner services field investigation/notification     |
| <input type="checkbox"/> Churches/temples/mosques                | <input type="checkbox"/> Events (e.g., health fairs, National HIV Testing Day) |
| <input type="checkbox"/> Other outreach (please describe):       |  |

4. In approximately how many **sites or programs** does the health department support rapid HIV testing? *Note: An agency may operate multiple sites or programs where rapid HIV testing is provided (e.g., an emergency department and a primary health clinic operated by one hospital represent two distinct sites). We are interested in the number of distinct sites where rapid HIV testing is provided.*

- a. How many distinct **agencies** are represented by all of the sites and programs included in response to question 4?

5. Does the health department support any programs/agencies to provide routine testing (i.e., screening) for HIV in health care settings? *By routine testing we mean voluntary HIV testing performed for all patients in a population unless the patient declines HIV testing.*

Yes  No  Don't know

- a. If "Yes" to Question 5, is rapid HIV testing used by any of these programs/agencies?  
 Yes  No  Don't Know

b. If "Yes" to Question 5a, please indicate the settings in which routine testing using rapid HIV tests is provided:

- |   |   |
|---|---|
| <input type="checkbox"/> STD clinics                          | <input type="checkbox"/> Family planning clinics        |
| <input type="checkbox"/> Community health centers             | <input type="checkbox"/> Hospital emergency departments |
| <input type="checkbox"/> Substance abuse treatment facilities | <input type="checkbox"/> Urgent care clinics            |
| <input type="checkbox"/> Prenatal/obstetrical clinics         | <input type="checkbox"/> Hospital inpatient             |
| <input type="checkbox"/> Labor and delivery                   | <input type="checkbox"/> TB clinics                     |
| <input type="checkbox"/> Primary care clinics                 | <input type="checkbox"/> Correctional facilities        |
| <input type="checkbox"/> Other (please describe):             |   |

6. In the following table, please indicate the number of HIV tests that health department supported programs conducted during 2006 and the estimated number that will be conducted in 2007 and 2008: *Note: please provide the total number of tests in the last row of the table below even if you are unable to provide a breakdown by type of test or specimen.*

Tests and Specimen Type	2006 (Actual)	2007 (Estimated)	2008 (Estimated)
Standard laboratory tests using venipuncture or dried blood spot			
Standard laboratory tests using oral fluid			
Standard laboratory tests but specimen type cannot be determined			
Rapid HIV tests conducted using fingerstick or venipuncture			
Rapid HIV tests conducted using oral fluid			
Rapid HIV tests but specimen type cannot be determined			
<b>Total number of HIV tests conducted by health department supported programs (regardless of type of tests or specimen)</b>			

7. If you anticipate a decrease in the number of rapid tests to be conducted in 2008 compared with 2007, please indicate the reason(s). (*Check all that apply*)

- End of CDC bulk purchase program
- Reductions in federal funding for HIV prevention
- Reductions in state/local funding for HIV prevention
- Change in program priorities
- State/local health department capacity
- Local provider capacity
- Test sensitivity
- Test specificity
- Other (please describe)

8. **Between June 2006 and June 2007**, which rapid HIV tests were used by health department supported programs? (*Check all that apply*)

- Clearview Complete
- Clearview (StatPak)
- Multi-spot
- OraQuick *Advance*
- Reveal
- UniGold

a. If you checked more than one test in response to Question 8, was use of multiple rapid HIV tests part of a research study?  Yes  No  Don't know

9. **Since July 2007**, which rapid HIV tests have been used by health department supported programs? (*Check all that apply*)

- Clearview Complete
- Clearview (StatPak)
- Multi-spot
- OraQuick *Advance*
- Reveal
- UniGold

a. If you checked more than one test in response to Question 9, was use of multiple rapid HIV tests part of a research study?  Yes  No  Don't know

10. In 2008, which rapid HIV test(s) do you intend to use? (*Check all that apply*)

- Clearview Complete
- Clearview (StatPak)
- Multi-spot
- OraQuick *Advance*
- Reveal
- UniGold
- Under consideration, decision pending
- Don't know

a. What factors determined the rapid HIV test(s) you will use in 2008? (*Check all that apply*)

- Sensitivity
- Specificity
- Price
- Run time
- Read window
- Ease of specimen collection
- Approved for oral specimens
- Ease of reading results
- Ease of performing test
- Approved for HIV-2
- Length of shelf life (tests)
- Length of shelf life (controls)
- Operating temperature
- Storage temperature
- Ease of integration into service/clinic flow
- Other (please describe):

- b. Please rank, the three the most important factors that determined the test(s) you will use in 2008, with “1” being the “most important” factor.

Sensitivity  
Specificity  
Price  
Run time  
Read window  
Ease of specimen collection  
Approved for oral specimens  
Ease of reading results  
Ease of performing test  
Approved for HIV-2  
Length of shelf life (tests)  
Length of shelf life (controls)  
Operating temperature  
Storage temperature  
Ease of integration into service/clinic flow  
Other (please describe):

## PROCUREMENT

*The questions in this section address procurement of rapid HIV tests by the health department.*

11. In 2007, approximately how many rapid HIV tests will have been purchased by the health department:

- ◆ Directly by the HIV prevention program
- ◆ Through another state/local department or organizational unit within the health department (e.g., laboratory or pharmacy)
- ◆ Through an intermediary entity (e.g., hospital, clinic or CBO/ASO)
- ◆ Through the 340 B program
- ◆ Other: (please describe):

12. In 2008, what mechanism(s) will you use for purchasing rapid tests within your jurisdiction?

*(Check all that apply)*

- Health department procurement process (please describe):
- Health department HIV prevention program negotiates directly with companies and purchases through health department procurement process
- Health department HIV prevention program negotiates directly with companies and purchases *outside* of health department procurement process
- Another state/local department or organizational unit within the health department (e.g., the laboratory or pharmacy) purchases devices
- Resources are directed to an intermediary entity (e.g., a hospital, clinic, or CBO/ASO) to purchase devices for the program
- Funding is provided to grantees and other local service providers to purchase devices

- 340 B program
- Other (please describe):

13. In 2008, approximately how many rapid HIV tests will be purchased by the health department:

- ◆ Directly by the HIV prevention program
- ◆ Through another state/local department or organizational unit within the health department (e.g., laboratory or pharmacy)
- ◆ Through an intermediary entity (e.g., hospital, clinic or CBO/ASO)
- ◆ Through the 340 B program
- ◆ Other (Please describe):

14. Approximately how many of each of the following rapid HIV test devices does the health department anticipate **purchasing** in 2008? (Check only one box in each column)

Number of Tests	<u>Clearview Complete</u>	<u>Clearview (StatPak)</u>	<u>Multi-Spot</u>	<u>OraQuick Advance</u>	<u>Reveal</u>	<u>UniGold</u>
None	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Less than 1,000	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1,001-5,000	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5,001 – 10,000	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10,001 – 15,000	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15,001-25,000	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25,001-50,000	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
50,001-75,000	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
75,001-100,000	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Greater than 100,000	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Not yet determined	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## PERFORMANCE

The questions in this section address performance of HIV rapid tests used by your program. You are encouraged to consult closely with your public health laboratory partners in responding to questions in this section.

15. From June 2005 through today's date, did any sites experience a cluster of excess false-positive rapid test results? *A cluster is defined as an unexpected increase in false-positive rapid test results within a defined time period.*  Yes  No  Don't know
- a. If "Yes" to Question 15, beginning with the most recent cluster and working back in time, please provide the total number of false-positive rapid HIV test results, true-positive rapid HIV test results, negative rapid HIV test results, and the time period (date to date) for up to three of these clusters.

Cluster	Time Period	Total False-Positive Tests	Total True-Positive Tests	Total Negative Tests
1				
2				
3				

- b. If “Yes” to Question 15, which rapid tests were involved in the cluster(s) of false-positive rapid test results? (Check only one test per cluster)

<u>Cluster 1</u>	<u>Cluster 2</u>	<u>Cluster 3</u>
<input type="checkbox"/> Clearview Complete	<input type="checkbox"/> Clearview Complete	<input type="checkbox"/> Clearview Complete
<input type="checkbox"/> Clear view (StatPak)	<input type="checkbox"/> Clearview (StatPak)	<input type="checkbox"/> Clearview (StatPak)
<input type="checkbox"/> Multispot	<input type="checkbox"/> Multispot	<input type="checkbox"/> Multispot
<input type="checkbox"/> OraQuick <i>Advance</i>	<input type="checkbox"/> OraQuick <i>Advance</i>	<input type="checkbox"/> OraQuick <i>Advance</i>
<input type="checkbox"/> Reveal	<input type="checkbox"/> Reveal	<input type="checkbox"/> Reveal
<input type="checkbox"/> Unigold	<input type="checkbox"/> Unigold	<input type="checkbox"/> Unigold

The following questions apply for any/all of the clusters described in response to 15a.

- c. Did you notify the manufacturer(s) of the rapid test about the cluster(s) of false-positive rapid HIV test results?  Yes  No
- d. Did you investigate further the possible cause(s) of the cluster(s) of false-positive rapid HIV test results?  Yes  No
- e. If “Yes” to Question 15d, which of the following were part of your investigation?  
(Check all that apply)
- Review of quality control practices
  - Review of quality control documentation (including temperature logs, testing logs, etc)
  - Observation of test practices
  - Discussion of potential causative factors with rapid test operators
  - Worked in collaboration with manufacturer representatives
  - Other (please describe):
- f. If “Yes” to Question 15d, which of the following reasons (if any) were thought to play a role in the cluster of false-positive rapid HIV test results?
- ◆ Over collection of specimen  Yes  No  Don't know  Not investigated
  - ◆ Out of range storage temperature  Yes  No  Don't know  Not investigated
  - ◆ Out of range operating temperature  Yes  No  Don't know  Not investigated
  - ◆ Not reading test results in the correct time frame  Yes  No  Don't know  Not investigated
  - ◆ Mix up of patient specimens  Yes  No  Don't know  Not investigated
  - ◆ Other reasons (please describe):

## USE OF COMBINATIONS OF RAPID HIV TESTS AT INDIVIDUAL TEST SITES

The questions in this section address use of multiple rapid HIV tests at one or more of your rapid HIV test sites/programs. You are encouraged to consult closely with your public health laboratory partners in responding to questions in this section.

16. Do one or more of your rapid HIV test sites routinely run one or more additional rapid test(s) in a sequential algorithm to retest initial reactive results for clients during the same visit?  
*“Sequential” means that only one rapid test is used as the screening test (i.e., in the first step of the algorithm).*  Yes  No  Don't know

- a. If “Yes” to Question 16, does the health department require this standard of practice or is it a standard of practice adopted by individual site(s)?

- Health department required standard of practice  
 Standard practice adopted by one or more individual sites  
 Don't know

- b. Is the use of multiple rapid HIV tests in a serial algorithm part of a research study?  Yes  
 No  Don't know

- c. If “yes” to question 16, at how many different sites is a serial multiple rapid HIV test algorithm used? *An agency may operate multiple sites or programs where rapid HIV testing is provided. We are interested in the number of distinct sites where rapid HIV testing is provided.*

- d. If “yes” to question 16, how many different sequential algorithms have been implemented in your jurisdiction? *(Check one)*  
 1  2  3  4 or more  Don't know

- e. For this algorithm, which rapid HIV test(s) is/are used *FIRST* to test the client?

HIV Rapid Test	Oral Fluid	Fingerstick Whole Blood	Venipuncture
Clearview Complete		<input type="checkbox"/>	<input type="checkbox"/>
Clearview (StatPak)		<input type="checkbox"/>	<input type="checkbox"/>
Multispot		<input type="checkbox"/>	<input type="checkbox"/>
OraQuick <i>Advance</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Reveal		<input type="checkbox"/>	<input type="checkbox"/>
Unigold		<input type="checkbox"/>	<input type="checkbox"/>

- f. Which rapid HIV test(s) is/are used as the *SECOND* test to retest the preliminary positive client during the same visit?

HIV Rapid Test	Oral Fluid	Fingerstick Whole Blood	Venipuncture
Clearview Complete		<input type="checkbox"/>	<input type="checkbox"/>
Clearview (Stat Pak)		<input type="checkbox"/>	<input type="checkbox"/>
Multispot		<input type="checkbox"/>	<input type="checkbox"/>
OraQuick <i>Advance</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Reveal		<input type="checkbox"/>	<input type="checkbox"/>

UniGold

- g. Which rapid HIV test(s) is/are used as the *THIRD* test to retest the preliminary positive client during the same visit? (Leave blank if a third test is not used in the algorithm)

HIV Rapid Test	Oral Fluid	Fingerstick Whole Blood	Venipuncture
Clearview Complete		<input type="checkbox"/>	<input type="checkbox"/>
Clearview (Stat Pak)		<input type="checkbox"/>	<input type="checkbox"/>
Multispot		<input type="checkbox"/>	<input type="checkbox"/>
OraQuick <i>Advance</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Reveal		<input type="checkbox"/>	<input type="checkbox"/>
UniGold		<input type="checkbox"/>	<input type="checkbox"/>

17. Do one or more of your rapid HIV test sites/programs routinely use two or more rapid HIV tests in a parallel algorithm? *“Parallel” means that at least two rapid tests are used together (i.e., at least two screening tests).*  Yes  No  Don't know

- a. If “Yes” to Question 17, does the health department require this standard of practice or is it a standard of practice adopted by individual site(s)?

- Health department required standard of practice  
 Standard practice adopted by one or more individual sites  
 Don't know

- b. Is use of multiple rapid HIV tests in a parallel algorithm part of a research study?  Yes  No  Don't know

- c. At how many different sites is a parallel rapid HIV test algorithm implemented?

- d. If “Yes” to Question 17, how many different parallel algorithms are used? (Check one)  
 1  2  3  4 or more  Don't know

- e. Which rapid HIV test(s) is/are used in a parallel algorithm?

HIV Rapid Test	Oral Fluid	Fingerstick Whole Blood	Venipuncture
Clearview Complete		<input type="checkbox"/>	<input type="checkbox"/>
Clearview (StatPak)		<input type="checkbox"/>	<input type="checkbox"/>
Multispot		<input type="checkbox"/>	<input type="checkbox"/>
OraQuick <i>Advance</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Reveal		<input type="checkbox"/>	<input type="checkbox"/>
UniGold		<input type="checkbox"/>	<input type="checkbox"/>

## FUTURE PLANS AND TECHNICAL ASSISTANCE NEEDS

The questions in this section address your plans for use of rapid HIV testing in 2008 as well as any technical assistance and/or training needs you have in conjunction with rapid HIV testing programs.

18. In 2008, will you be increasing, decreasing or keeping the same the number of sites using rapid HIV testing? *Note: An agency may operate multiple sites where rapid HIV testing is provided. We are interested in the number of distinct sites where rapid HIV testing is provided (e.g., an emergency department and a primary health clinic operated by one hospital represent two distinct sites).*

- We will be increasing the number of sites using rapid HIV testing
- We will be keeping the same number of sites using rapid HIV testing
- We will be decreasing the number of sites using rapid HIV testing
- Don't know

a. If you expect to **increase** the number of sites using rapid HIV testing, in which types of venues/settings do you plan to implement rapid HIV testing? (*Check all that apply*)

- |  |   |
|--|---|
| <input type="checkbox"/> PCRS program                      | <input type="checkbox"/> Prenatal/obstetrical clinics   |
| <input type="checkbox"/> CBOs/ASOs ( <i>on-site only</i> ) | <input type="checkbox"/> Labor and delivery             |
| <input type="checkbox"/> Substance abuse treatment         | <input type="checkbox"/> Community health centers       |
| <input type="checkbox"/> HIV testing sites                 | <input type="checkbox"/> Family planning clinics        |
| <input type="checkbox"/> Outreach venues                   | <input type="checkbox"/> TB clinics                     |
| <input type="checkbox"/> Local health departments          | <input type="checkbox"/> Colleges                       |
| <input type="checkbox"/> Correctional facilities           | <input type="checkbox"/> Hospital emergency departments |
| <input type="checkbox"/> STD clinics                       | <input type="checkbox"/> Primary care clinics           |
| <input type="checkbox"/> Urgent care clinics               | <input type="checkbox"/> Other (please describe):       |

b. If you expect to **increase** the number of sites providing rapid HIV testing, approximately how many additional sites that you support will offer rapid testing?

c. If you expect to **decrease** the number of sites/programs providing rapid HIV testing, what are the reasons?

- Lack of resources
- Lack of health department capacity
- Lack of local provider capacity
- No clear programmatic use
- Lack of yield of positives
- Performance of rapid tests
- Rapid testing is supported by other state agencies
- Rapid testing is supported by other funding sources
- Other (please describe):

19. Please indicate any technical assistance needs associated with rapid HIV testing which cannot be addressed by your health department. (*Check all that apply*)

- Laboratory training for health department staff
- Laboratory training for local providers
- Test device training (indicate specific device):
- Counselor training
- Evaluating the impact of rapid HIV testing
- Evaluating the cost effectiveness of rapid HIV testing
- Validating rapid HIV tests from various manufacturers
- Adopting multi-test algorithms

- Identifying appropriate venues and/or populations to implement rapid testing
- Providing rapid testing in specific venues or settings: (please describe):
- Other (please describe):

**Thank you for taking the time to complete this survey.**  
**If you have any questions or comments regarding this survey please contact**  
**Connie M. Jorstad at [cjorstad@NASTAD.org](mailto:cjorstad@NASTAD.org) or by phone at (202) 434-7128.**

*NOTE: Because of the nature of online surveying, the question wording, formatting and skip patterns in this version of the survey tool may not have matched, exactly, the online version of the survey.*

**Appendix B: HIV Rapid Tests to be Used in Health Department Supported Programs, 2008**

Jurisdiction	Clearview Complete	Clearview	MultiSpot	OraQuick Advance	Reveal	UniGold	Decision Pending	Don't Know
Alaska				Yes				
Arizona							Yes	
California				Yes				
Chicago				Yes			Yes	
Colorado				Yes		Yes		
Connecticut		Yes		Yes			Yes	
Delaware						Yes	Yes	
Florida				Yes		Yes		
Hawaii				Yes			Yes	
Iowa				Yes				
Idaho		Yes		Yes				
Illinois				Yes			Yes	
Indiana								Yes
Kansas							Yes	
Louisiana		Yes		Yes		Yes		
Los Angeles		Yes		Yes		Yes		
Massachusetts		Yes		Yes		Yes	Yes	
Maryland				Yes			Yes	
Maine				Yes				
Michigan		Yes		Yes		Yes	Yes	
Minnesota				Yes		Yes		
Missouri				Yes				
Montana				Yes			Yes	
North Carolina		Yes		Yes		Yes		
Nebraska	Yes	Yes		Yes		Yes		
New Hampshire				Yes			Yes	
New Jersey		Yes		Yes		Yes		
New York	Yes	Yes		Yes		Yes		
New York City	Yes	Yes		Yes		Yes		
Ohio		Yes		Yes		Yes		
Oklahoma				Yes		Yes		
Oregon							Yes	
Pennsylvania				Yes				
Philadelphia				Yes		Yes		
South Carolina				Yes			Yes	
San Francisco		Yes		Yes		Yes	Yes	
Tennessee				Yes				
Texas		Yes		Yes		Yes		
Utah	Yes	Yes		Yes				
Virginia		Yes		Yes				
Vermont				Yes				
Washington				Yes		Yes		
Wisconsin		Yes		Yes				
Wyoming	Yes			Yes		Yes	Yes	