**Rapid HIV Testing Assessment**
**October 2006**

## Introduction

NASTAD has long supported rapid HIV testing technology and was among those organizations instrumental in advocacy to obtain Food and Drug Administration (FDA) approval of rapid testing technology along with the Clinical Laboratory Improvement Amendments (CLIA) waiver that allowed their use without regulatory oversight, particularly in non-clinical settings. With the approval of this technology, health departments have implemented rapid testing in high-risk and other settings, resources permitting. Shortage of resources continues to further constrain implementation of rapid testing technology, in spite of the effectiveness and successes associated with it. In order to help guide policy and future HIV testing programs in the United States, NASTAD recently conducted a survey of state and directly funded health departments.

The survey was designed to better understand the utilization of rapid HIV testing and to determine:

- Mechanisms and resources used by health departments to procure rapid HIV test devices
- Types of technologies and volume of tests conducted by health department supported testing programs
- Venues in which rapid HIV testing is conducted
- Health department priorities for expansion of rapid HIV testing

The nine-item survey tool was distributed to all state and directly funded AIDS program directors and prevention program managers in May 2006. In June, all AIDS program directors were sent a reminder, via email, to complete and return the survey. Follow-up was conducted in early August with jurisdictions who had not yet completed and returned the survey questionnaire. A total of 43 completed responses, representing 39 state health departments, three city health departments and one territorial health department comprised the final sample.

The results of the survey are as follows:

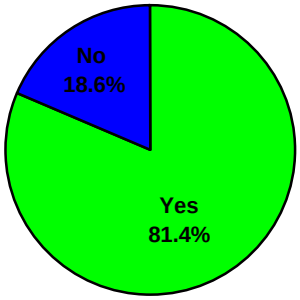
## Current Status of Rapid HIV Testing

Respondents were asked to indicate whether or not their health department currently supported a rapid testing program[1]. As indicated in Figure 1 below, of the 43 respondents, 35 (81.4 percent)

[1] In responding to this question, health departments were asked to exclude any organizations/agencies which are supported only by the CDC to provide rapid HIV testing.

indicated they supported a rapid testing program. Only eight (8) health departments reported that they do not currently support a rapid HIV testing program.

**Figure 1. Percent of Health Departments Supporting Rapid Testing (N=43)**




Among the eight health departments not currently supporting rapid HIV testing, six cited a lack of resources as a primary barrier and four cited a lack of health department infrastructure. Statutory/regulatory barriers were reported by two of the eight respondents. Lack of local provider capacity, no clear programmatic use, support by federal agencies and lack of laboratory capacity also received mention. Of the eight health departments not supporting rapid HIV testing, four indicated they planned to implement rapid HIV testing within the next 12 months, while three reported no plans to implement rapid HIV testing and one was unsure of implementation plans.

## Volume of HIV Testing

A total of 39 health departments (90.6 percent of all respondents) indicated plans to support rapid HIV testing during the 12 months subsequent to the survey. These respondents were asked to report the number of conventional and rapid HIV tests conducted jurisdiction-wide during 2005. They were also asked to estimate the number of conventional and rapid tests anticipated to be conducted in 2006. These data are presented below in Table 1.

**Table 1. Actual and Estimated HIV Test Volume: 2005 and 2006 (N=39)**

| | Total Test Volume |
|---|---|
| Conventional Tests (2005) | 1,358,644 |
| Estimated Conventional Tests (2006) | 1,236,382 |
| Rapid Tests (2005) | 445,063 |
| Estimated Rapid Tests (2006)[2] | 613,850 |

All 39 health departments planning to use rapid testing reported that they expect to continue to use conventional HIV testing in combination with rapid testing. Conventional tests accounted

[2] One respondent indicated plans to continue rapid testing in 2006, but did not provide an estimate of the number of tests performed.

for a majority of HIV tests conducted during 2005 and are expected to continue to account for the majority of all tests conducted during 2006.

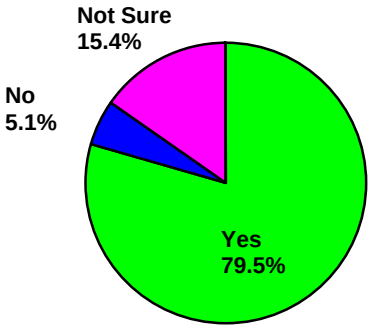
As illustrated above in Table 1, respondents projected an 8.9 percent decrease in the total number of conventional tests conducted in 2006 when compared with 2005. At the same time, a 37.9 percent increase in the total number of rapid HIV tests is projected in 2006, compared with 2005. When rapid and conventional test projections are combined, health departments anticipate an overall increase of just 2.6 percent in total volume of tests conducted.

Five health departments indicated that they expected that the volume of rapid tests conducted in the jurisdiction would decrease in 2006, when compared with 2005. Three of these jurisdictions attributed this decrease to reductions in federal funding for HIV prevention and three attributed the decrease to the end of federal bulk purchases of rapid HIV tests. One jurisdiction attributed decreased volume of rapid tests to the end of CDC-funded demonstration project while another indicated reduction in health department staffing would result in decreased volume of rapid testing.[3] Across these five jurisdictions, the total volume of rapid tests performed in 2006 was estimated at 67,000 compared with 88,260 for 2005. This represents a decrease of 24.1 percent in the total number of rapid tests performed. The median estimated volume of rapid tests for 2006 in these five jurisdictions was 16,500 compared with 23,754 in 2005.

## Demand for Rapid HIV Testing

Health departments were asked to indicate whether or not the demand for rapid tests has increased, regardless of plans for purchase of rapid HIV tests during 2006. Responses to this item are presented below in Figure 2.

**Figure 2. "Has the demand for rapid tests increased?" (N=39)**




While a majority (79.5 percent) of the 39 responding health departments indicated that the demand for rapid tests had increased, only 14 (45.2 percent) health departments reported that they could document increased demand, while 16.1 percent indicated that they could not document an increase and 38.7 percent were "not sure" whether they could document an increase in demand for rapid tests.

[3] Respondents could indicate multiple reasons for decreased test volume.

Of the 11 health departments that indicated the magnitude of increase, the majority (54.6 percent) reported an increase in volume of 10 percent or less, two respondents reported a 20 to 25 percent increase, one health department reported a 37 percent increase and one reported a 48 percent increase in test volume.

## Implementation of Rapid Testing

Health departments were asked to report the venues and or settings in which they are conducting HIV testing using rapid tests. These data are described below in Table 2.

**Table 2. Venues and Settings where Rapid Testing is Conducted (N=43)**

| Venue | Percent | Venue | Percent |
|---|---|---|---|
| Outreach | 81.4 % | Labor and delivery | 25.6 % |
| HIV test sites | 72.1 % | Colleges | 25.6 % |
| CBOs/ASOs (on-site) | 69.8 % | Primary care clinics | 25.6 % |
| STD Clinics | 67.4 % | Family planning clinics | 23.3 % |
| Local health departments | 60.5 % | Hospital emergency depts. | 18.6 % |
| Correctional settings | 46.5 % | TB clinics | 16.3 % |
| Community health clinics | 46.5 % | Prenatal/obstetrical | 14.0 % |
| Drug treatment | 41.9 % | Other (e.g., urgent care, shelters, "non-traditional" sites) | 7.0 % |
| PCRS programs | 37.2 % | | |

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 below in Table 3.

**Table 3. Outreach Settings Where Rapid Testing is Conducted (N=35)**

| Setting | Percent |
|---|---|
| Special events | 85.7 % |
| Mobile van | 60.0 % |
| Bars | 45.7 % |
| Homeless shelters | 40.0 % |
| Street outreach | 34.3 % |
| Parks | 25.7 % |
| Bathhouses | 25.7 % |
| Drug selling sites | 17.1 % |
| House parties | 8.6 % |
| Beauty/barber shop | 0.0 % |
| Other (e.g., storefront sites, churches/faith based venues, National HIV Test Day, "stroll") | 17.1 % |

## Priorities for Expansion of Rapid Testing

Setting aside resource and policy constraints, health departments were asked to indicate priority venues/settings for expansion of rapid testing within their jurisdiction. Outreach programs were

cited by a majority of respondents as a priority. PCRS programs, "free-standing" HIV test sites, and community-based organizations were also high priorities. Responses to this item are presented below in Table 4.

**Table 4. Priority Venues for Expanded Use of Rapid Testing (N=43)**

| Venue | Percent |
|---|---|
| Outreach programs | 51.2 % |
| PCRS programs | 37.2 % |
| HIV Test Sites | 32.6 % |
| CBOs/ASOs | 30.2 % |
| Community health clinics | 25.6 % |
| STD clinics | 23.3 % |
| Hospital emergency departments | 23.3 % |
| Correctional settings | 11.6 % |
| Drug treatment facilities | 9.3 % |
| Local health departments | 7.0 % |
| Primary care clinics | 4.7 % |
| Prenatal/obstetrical clinics | 2.3 % |
| Colleges | 2.3 % |
| Family planning clinics | 0.0 % |
| TB clinics | 0.0 % |
| Other (e.g., urgent care clinics, shelters, labor and delivery) | 9.3 % |

## Technical Assistance in Support of Rapid Testing

Respondents indicated a variety of technical assistance (TA) needs related to supporting and sustaining implementation of rapid testing. These are presented below in Table 5.

**Table 5. Technical Assistance Needs (N=43)**

| TA Need | Percent |
|---|---|
| Evaluating the impact of rapid testing | 51.2 % |
| Evaluating the cost-effectiveness of rapid testing | 44.2 % |
| Test device training | 39.5 % |
| Laboratory training for local providers | 30.2 % |
| Counselor training | 27.9 % |
| Laboratory training for health department staff | 18.6 % |
| Identifying appropriate venues and/or populations for rapid testing | 16.3 % |
| Providing rapid testing in specific venues or settings (e.g., primary care clinics, bars) | 14.0 % |
| Other (e.g., supervision, quality assurance, integration into outreach, CLIA issues) | 14.0 % |

A majority of responding health departments (51.2 percent) indicated a need for assistance in evaluating the impact of rapid testing and a sizeable minority indicated a need for assistance in evaluating the cost-effectiveness of rapid testing.

## Procurement of Rapid HIV Tests

Respondents were asked to indicate the number of rapid tests obtained in 2005 through various procurement mechanisms, as described below in Table 6.

**Table 6. Procurement of Rapid Tests 2005 (N=35)**

| | # of Health Departments | Total # of Tests |
|---|---|---|
| Purchase via health department procurement process | 23 (65.7 %) | 533,621 |
| Purchase through bulk purchase program | 5 (14.3 %) | 69,900 |
| Receive through CDC bulk purchase | 13 (37.1 %) | 114,045 |
| Obtain through other mechanism | 11 (31.4 %) | 118,370 |

Of the 23 health departments that indicated purchasing rapid HIV tests through health department procurement processes, nine reported also receiving rapid tests via the CDC bulk purchase and five obtained rapid tests through other mechanisms. Of the 13 health departments participating in the CDC bulk purchase, nine purchased their own rapid tests and four obtained tests from other mechanisms including the SAMHSA bulk purchase and "roll-over" of devices obtained in 2004.

Health departments were asked to describe anticipated purchase, by the health department HIV prevention program, of rapid tests for calendar year 2006. These data are presented below in Table 7.

**Table 7. Anticipated Purchase Volume of Rapid Tests for 2006 (N=35)**

| Number of Tests | OraQuick | UniGold | Reveal | Multi Spot |
|---|---|---|---|---|
| <1,000 | 2 (6.5 %) | 5 (45.5 %) | 1 (100.0 %) | 2 (100.0 %) |
| 1,001 – 10,000 | 17 (54.8 %) | 5 (45.5 %) | 0 | 0 |
| 10,001 – 25,000 | 7 (22.6 %) | 1 (9.0 %) | 0 | 0 |
| 25,001 – 50,000 | 4 (12.9 %) | 0 | 0 | 0 |
| 50,001 – 75,000 | 1 (3.2 %) | 0 | 0 | 0 |
| 75,001 – 100,000 | 0 | 0 | 0 | 0 |
| > 100,000 | 0 | 0 | 0 | 0 |

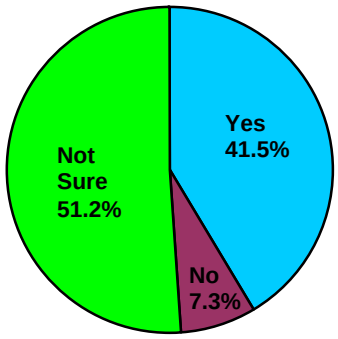
A majority (88.5 percent) of respondents indicated plans to purchase OraQuick in 2006. Of the respondents, nearly one-third (29.0 percent) also reported plans to purchase UniGold. Two of these jurisdictions also planned to purchase MultiSpot and one indicated that Reveal would also

be purchased. Of the 11 health departments that plan to purchase UniGold, two currently use this product exclusively, while an additional two plan to use this product exclusively.

Respondents were asked to describe the mechanisms used for purchasing rapid tests. Of the 32 health departments that responded to this item, 40.6 percent indicated that they use a state procurement process, involving bids, request for proposals or similar mechanisms. Another 21.9 percent reported negotiating directly with companies and purchasing via state procurement processes, 15.6 percent reported negotiating directly with companies and purchasing outside of state procurement processes, such as through a third-party vendor and 9.4 percent indicated that resources are directed to another state entity (e.g., laboratories) which purchases tests for the HIV/AIDS program and/or its grantees.

Health departments were asked whether it was permissible within their jurisdiction to purchase rapid tests through a 340B program. As illustrated below in Figure 3, a majority (51.2 percent) of health departments are "not sure" whether state and/or local regulations allow for purchase of rapid HIV tests through a 340B program such as a sexually transmitted disease clinic or AIDS Drug Assistance Program.

**Figure 3. "Do state/local regulations allow purchase of rapid tests through 340B entity?" (N=43)**




For the 17 (41.5 percent) health departments that indicated that state/local regulations allowed for purchase of rapid tests through a 340B program, nine (56.3 percent) reported that they could purchase rapid tests on behalf of agencies that received direct funding, although half of these indicated that a mechanism other than reimbursement would be required. The remaining seven (43.8 percent) of the health departments indicated that they were "not sure" whether they could purchase rapid test kits on behalf of agencies receiving funding directly from the CDC.

Health departments with access to 340B programs were asked whether a lower price would result in their purchasing more rapid test kits. Of these 17, the majority (69.2 percent) were "not sure" whether they would purchase more rapid test than they currently do. Only two health departments indicated that they would purchase more rapid tests than they currently do and the remaining two indicated they would purchase the same number of tests, but direct "savings" elsewhere.

## Discussion

A large majority (81.4 percent) of health departments indicate that they have implemented rapid HIV testing. Further, rapid testing is supported in a wide variety of venues, including clinical settings which have been identified through CDC's *Advancing HIV Prevention* initiative as high priorities for expansion of HIV testing. Health departments have identified venues/settings for targeted testing, such as CBOs and PCRS programs, as priorities for expanded use of rapid testing. Clinical settings such as STD clinics, community health clinics and hospital emergency departments were also identified as priorities for expanded use of rapid testing.

Health departments participating in this assessment reported using a mix of test technologies, with the vast majority of tests conducted using conventional technologies. Based on respondent estimates, the number of rapid tests that are expected to be conducted in 2006 will increase by 38 percent compared with 2005. At the same time, the number of conventional tests is expected to decrease by almost nine percent. Even with a relatively sizeable projected increase in the number of rapid tests, the overall volume of tests performed is expected to increase in 2006 by only 2.5 percent compared with 2005. Coupled with the finding which suggests a very modest increase in demand for rapid testing, this highlights an important question regarding the extent to which CDC's continuing emphasis on expansion of rapid HIV testing will contribute to a substantial increase in the uptake of HIV testing.

While several respondents indicated receiving rapid tests through participation in federal bulk purchase programs, the vast majority of health departments responding to this survey indicated they also purchased rapid tests. Overall, the volume of rapid tests conducted by responding jurisdictions is expected to increase in 2006. Relatively few health departments indicated that they expected to conduct fewer rapid tests in 2006, compared with 2005. Only three health departments indicated that the decrease in test volume was linked specifically to the end of the CDC bulk purchase program. These findings suggest that health departments are redirecting state and federal resources from other programmatic activities to support purchase of rapid test devices, underscoring their commitment to sustaining implementation of testing programs using rapid technologies.

Acquisition of rapid tests through a 340B program may possibly enable health departments to purchase rapid tests at a lower cost. Even so, most health departments are unsure whether state or local regulations will allow this. This suggests a need for additional investigation into the 340B or similar purchasing mechanisms for rapid tests. Continued reductions in federal HIV prevention funding, combined with competing program priorities and intensified requirements for program monitoring, evaluation and quality assurance will undoubtedly challenge health departments to sustain current rapid testing programs. Without new HIV prevention resources, further expansion of rapid testing, particularly into clinical settings, will be exceptionally challenging to health departments.

While a majority of health departments indicated using OraQuick rapid tests, one-third of respondents reported using one or more tests in addition to, or instead of, OraQuick. Information obtained through follow-up with these health departments indicates that rapid tests other than OraQuick are used because they are a better "fit" for the settings in which rapid HIV tests are

conducted and/or can be obtained at a lower cost when compared with OraQuick. This finding underscores the need for health departments to maintain flexibility with respect to the specific test technology adopted. This is particularly important in the context of any plans for future federal bulk purchase programs.

A majority of health departments (51.2 percent) indicated a need for assistance in evaluating the impact of rapid testing and a sizeable number indicated a need for assistance in evaluating the cost-effectiveness of rapid testing. These findings suggest that health departments need to better understand and, perhaps, defend the relatively sizeable, ongoing investment in rapid HIV testing, particularly in comparison with conventional testing. Such evaluation should be a priority area for support and assistance.