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*Nicotine, pH, and Moisture Content of Smokeless Tobacco — Continued*

tobacco contains known cancer-causing agents: nitrosamines, polycyclic aromatic hydrocarbons, and radioactive polonium (*1*). These findings underscore the need for intensive efforts to prevent children and adolescents from using any tobacco product, including smokeless tobacco, and to educate young users about the risks associated with smokeless tobacco.

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## Prenatal Discussion of HIV Testing and Maternal HIV Testing — 14 States, 1996–1997

In July 1995, the Public Health Service recommended that health-care providers counsel all pregnant women about human immunodeficiency virus (HIV) prevention and encourage testing for HIV infection (*1*) and, if indicated, initiate zidovudine therapy (*2*). To evaluate compliance with these recommendations, CDC analyzed population-based data on HIV counseling and testing during 1996–1997 from 14 states participating in the Pregnancy Risk Assessment Monitoring System (PRAMS). This report presents an analysis of survey data collected from 1996 through 1997; results indicate that HIV counseling and testing of pregnant women were common but varied by state, type of prenatal health-care provider, Medicaid status, and maternal demographic characteristics.

PRAMS is an ongoing, state-based surveillance system that collects information about maternal behaviors, attitudes, and experiences. Each month, PRAMS surveys a random sample of mothers who have given birth to live infants during the previous 2–6 months using stratified, systematic sampling of resident birth certificates. A questionnaire is mailed to each mother, and a follow-up questionnaire is mailed to nonrespondents. Nonrespondents then are contacted by telephone. Statistical weights are applied to account for sampling probability, nonresponse, and sampling frame coverage in each state. The annual state-specific response rate to the entire

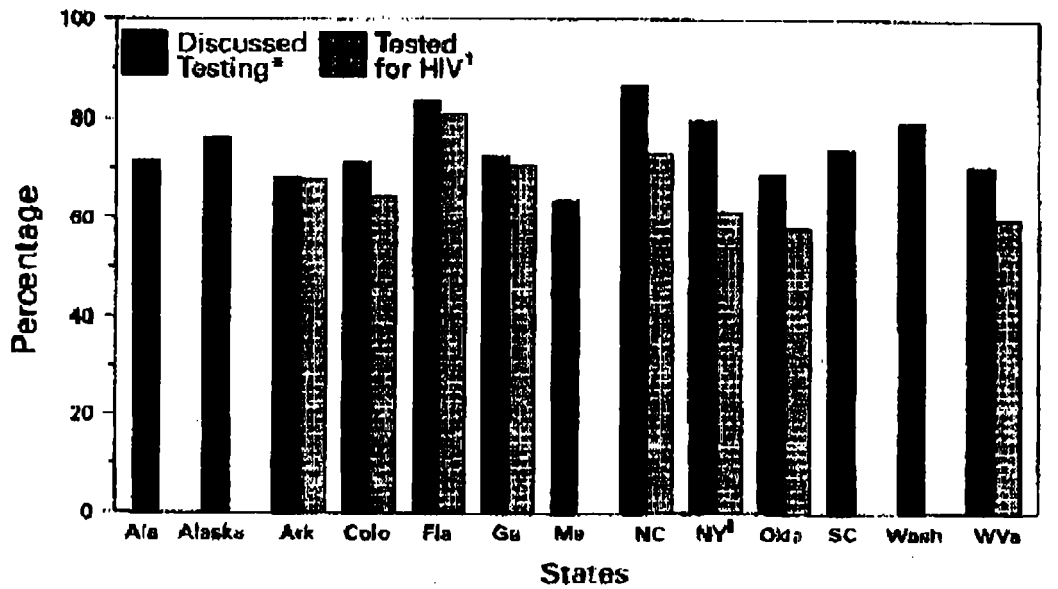
*Prenatal Discussion of HIV Testing — Continued*

questionnaire for 11 states in 1996 and 13 states in 1997 was approximately 70% (range: 69.4%–80.0%). Details of the survey design, questionnaire, and other operational aspects of the survey have been published (*3*).

Beginning in 1996, mothers who received prenatal care were asked whether a doctor, nurse, or other health-care provider counseled them about testing for HIV. Mothers in eight states, regardless of whether they received prenatal care, were asked if they had been tested for HIV infection during pregnancy or at delivery. Mothers who received any prenatal care and responded to the provider test discussion question were included in the analysis (n=17,354 [97.4%] in 1996; n=19,693 [98.1%] in 1997). To analyze maternal HIV testing, data were included on all mothers who responded to the HIV testing question regardless of having received prenatal care (n=8420 [89.8%] in 1996; n=11,152 [91.0%] in 1997). To account for the complex survey design, SUDAAN was used to calculate point estimates, risk ratios, and 95% confidence intervals (CIs) surrounding the risk ratios. State-specific risk ratios were considered significant if the 95% CI did not include 1. State-specific risk ratios are not presented for sparse data (response categories with <20 women).

During 1997, the state-specific proportion of mothers who recalled discussing HIV testing with their prenatal health-care provider ranged from 63.4% (Maine) to 86.7% (North Carolina), and the proportion of mothers who recalled being tested ranged from 58.0% (Oklahoma) to 80.7% (Florida) (Figure 1). Among 10 states with data from 1996 to 1997, increases in testing discussions occurred in New York (22.8%), Oklahoma (17.8%), and West Virginia (15.3%). Seven states demonstrated no increases

**FIGURE 1. Percentage of mothers who recalled discussing HIV testing with their health-care provider and percentage who reported being tested for HIV during pregnancy or at delivery, by state — 13 states, Pregnancy Risk Assessment Monitoring System, 1997**




*Includes only mothers who received prenatal care.
†Includes all mothers.
§Estimates do not include births in New York City.

*Prenatal Discussion of HIV Testing — Continued*

(range: –2 to 0.9%) in prenatal testing discussions. The largest increase in reporting of maternal testing from 1996 to 1997 occurred in New York (18.1%). Smaller increases occurred in West Virginia (15.2%), Florida (14.3%), Oklahoma (11.5%), and Georgia (6.5%).

During 1997 in all states, black mothers were significantly more likely than white mothers to report that their provider discussed testing (risk ratio [RR]=1.05–1.29). Hispanic mothers were not significantly more likely to report having had a testing discussion in most states. In seven states, mothers with less than a high school education were significantly more likely (RR=0.96–1.22) to recall a discussion about testing. Similarly, in 11 states, mothers aged <25 years were significantly more likely to recall a discussion about testing (RR=1.04–1.25). Public health-care providers were more likely than private providers to discuss testing (RR=0.96–1.29) in 10 states. In 11 states, mothers who received Medicaid benefits during pregnancy were significantly more likely to report discussions with a health-care provider (RR=0.99–1.32).

In most states, black race, type of prenatal health-care provider, education level, age, and receipt of Medicaid benefits were associated significantly with maternal HIV testing. However, associations between maternal characteristics and testing discussions were stronger than associations between maternal characteristics and actual testing.

*Reported by: Pregnancy Risk Assessment Monitoring System Working Group, Div of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion; Div of HIV/AIDS Surveillance and Epidemiology, National Center for HIV, STD, and TB Prevention, CDC.*

**Editorial Note:** This report documents a substantial level of counseling about HIV testing and receipt of testing for women who have given birth since publication of the 1995 guidelines. In 1997, >70% of women in nine states recalled discussing HIV testing with their health-care provider during prenatal care, and at least 50% of women in all states reported being tested for HIV during pregnancy or at delivery.

Data from PRAMS suggest that physician practices regarding prenatal HIV testing discussions and prenatal maternal HIV testing may be influenced by state-specific variations in HIV seroprevalence rates among childbearing women and physician perceptions of maternal HIV risk factors. Health-care providers serving women in states with high HIV seroprevalence rates may be more aware of HIV prevention and may place higher priority on prenatal HIV prevention. For example, on average, fewer mothers (89.2%) in low HIV seroprevalence states (HIV seroprevalence rate among pregnant women <0.05%) recalled a discussion about testing compared with mothers (81.4%) in high seroprevalence states (seroprevalence rate >0.4%) (*4*). Maternal HIV testing demonstrated a similar association; fewer mothers (58.0%) in low seroprevalence states were tested compared with mothers (70.9%) in high seroprevalence states. Variations in testing discussions by maternal race, age, and Medicaid status may reflect targeted testing efforts by providers on the basis of known epidemiology of HIV among women in their area. In addition, perception of the mother's risk may influence whether a provider discusses HIV testing.

Differences in state legislation also may contribute to variations in HIV discussions and testing. During 1996, Florida and New York enacted legislation requiring that all health-care providers include HIV counseling during prenatal care. High levels of provider discussions on HIV testing reported in Washington and North Carolina can be

*Prenatal Discussion of HIV Testing — Continued*

attributed to legislation mandating this activity before 1996. In July 1997, Arkansas law required that providers test all pregnant women for HIV; however, that legislation probably did not affect results presented in this report. An association among legislation, discussions, and actual HIV testing cannot be established using PRAMS data (*5*).

Another survey has shown increased test counseling for women who were young and other than white, sought care from a public provider, and had low incomes (*6*). PRAMS data also are consistent with a provider survey that found variations in prenatal test counseling according to provider type (i.e., public versus private) and type of patient insurance (i.e., Medicaid versus other) (*7*).

The findings in this report are subject to at least four limitations. First, information about previous HIV testing among mothers and the testing date, if any, were not available. Second, the wording of the survey questions did not allow consideration of a cause-effect relationship between provider test counseling and maternal test acceptance. Third, information was not collected on maternal risk for HIV infection, context of test counseling (i.e., strength of provider encouragement), or reasons a mother refused testing. Finally, data were not available to estimate self-reported information accuracy; however, most respondents completed the questionnaire within 4 months of the infants' delivery, minimizing recall bias.

Data from this survey permit health-care professionals and policymakers to monitor ongoing health-care provider counseling and maternal testing. The results described in this report emphasize the need for increasing health-care providers'—especially private sector providers'—awareness of HIV testing during prenatal care to ensure that health-care providers counsel all pregnant women.

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*(Continued on page 411)*

# FACSIMILE

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta, GA 30333

November 18, 1998

Dear Colleague:

The November 18, 1998 issue of the *Journal of the American Medical Association* (*JAMA*) contains an article authored by Dr. Bernard M. Branson, who is in our Division of HIV/AIDS Prevention, Surveillance and Epidemiology. This important article, entitled "Home Sample Collection Tests for HIV Infection," describes the use of HIV home sample collection (HSC) tests and provides the demographic and behavioral characteristics of users.

The study analyzed the results of 174,316 HIV HSC tests during the first year of availability. The participants were a volunteer sample of consumers who used either of two HSC tests. Some of the important findings include:

- HSC tests were used by individuals who were at risk for HIV and by those who did not seek other testing.
- Of the 174,316 HSC tests that were voluntarily submitted, 0.9% were positive for HIV infection and 97% of all users called to learn their test results.
- Most users were male, white, and aged 25-34.
- Nearly 60% of all users and 49% of those who tested HIV-positive had never been tested before.
- Most HIV-positive users either had a source of medical care or received referrals.

We are hopeful that this characterization of the use of HSC tests will help State Health Departments and AIDS Service Providers assess their potential for more widespread use.

Reprints of this article may be obtained by calling *JAMA* at (312) 464-4594. Also, the full text of this article may be downloaded at http://www.cdc.gov/nchstp/od/new.htm .

Should you have any questions or need additional information, please feel free to call our Office of Communications at (404) 639-8063.

Sincerely,

Melissa B Shepherd

Melissa Shepherd
Associate Director for Communications
Director, Office of Communications
National Center for HIV, STD, and TB Prevention

cc: Dr. Branson
Dr. DeCock
Dr. Holtgrave

## Toward Optimal Laboratory Use

# Home Sample Collection Tests for HIV Infection

Bernard M. Branson, MD

**Context.**—Home sample collection (HSC) tests allow persons to test themselves for human immunodeficiency virus (HIV) infection at home without medical supervision. Characterizing the use of such tests can help assess their potential effect on public health efforts to prevent and control HIV.

**Objective.**—To describe use of HIV HSC tests.

**Design.**—Retrospective descriptive analysis from data collected by test manufacturers during 1996 and 1997.

**Setting.**—United States.

**Participants.**—Volunteer sample of consumers who used either of 2 HSC tests.

**Main Outcome Measures.**—Demographic and behavioral aspects of users.

**Results.**—During the first year of availability, 174 316 HIV HSC tests were submitted to the manufacturers for analysis; 0.9% of the results were positive for HIV, and 97% of all users called to learn test results. Survey responses from 70 620 HIV-negative and 865 HIV-positive users revealed that most were men, white, and aged 25 to 34 years; HIV prevalence was highest among nonwhites, aged 35 to 44 years, men who have sex with men, and injection drug users. Bisexual men accounted for a large proportion of HIV-positive users. Nearly 60% of all users and 49% of those who tested HIV positive had never been tested before. Telephone counselors found that 23% of HIV-positive users already had a source of follow-up care, 65% accepted referrals, and 12% had tested themselves to evaluate the effects of antiretroviral therapy.

**Conclusions.**—Home sample collection tests for HIV were used by persons who were at risk for HIV and by persons who did not use other testing. Most HIV-positive users either had a source of medical care or received referrals.

*JAMA.* 1998;280:1699-1701

IN 1996, the Food and Drug Administration (FDA) approved 2 products for home sample collection (HSC) for human immunodeficiency virus (HIV) testing. The HSC kits are marketed directly to consumers. Users perform a finger-stick to obtain a dried-blood spot specimen on filter paper. The specimen is identified by an anonymous code number and mailed directly to a laboratory for HIV antibody testing by enzyme immunoassay. Reactive specimens are confirmed by Western blot or immunofluorescence assay. The user calls a toll-free telephone number to obtain test results, counseling, and referrals. Persons with negative results may choose to speak with a counselor, but most receive a prerecorded message with their result and counseling information. All users who test positive or indeterminate and those whose specimen was unsuitable for testing are connected to a counselor who provides test results, counseling, and referrals or follow-up instructions.

Considerable debate preceded approval of HSC HIV testing. Proponents maintained that its availability would increase testing,[1] but opponents raised concerns about negative consequences after people received results by telephone and the possible negative effect on public health surveillance and control.[2] Under regulations that permit the postmarketing evaluation of products that are brought to market before all outstanding questions are resolved, the FDA required HSC product manufacturers to collect data on users and to share this information with public health officials.

This article describes users during the first year of HSC test availability and compares them with clients of publicly funded testing programs.

## METHODS

Data from both HSC kit manufacturers were included in this analysis. Demographic questions asked by the 2 manufacturers were comparable, but the methods used to elicit information differed.

Home Access Health Corporation (HAHC, Hoffman Estates, Ill) requires users to register their test kit before submitting a specimen. During this telephone registration, users are asked to provide demographic and behavioral information via Touch-Tone telephone. During a second call to obtain test results, users with negative results receive them and counseling via prerecorded message unless they elect to speak with a counselor. Users whose specimens are positive, indeterminate, or unsuitable for testing are connected to a counselor who may elicit additional demographic and risk information and who also enters a summary of the telephone interaction in a call log. Home Access Health Corporation provided line-listed data for July 1996 through September 1997 for this analysis, including both the demographic survey and the call log.

Direct Access Diagnostics (DAD, Bridgewater, NJ) used a pamphlet included with the HSC test kit to provide pretest counseling information. The users' first contact with the company took place when they called for results. Users were asked for demographic and behavioral information after they received their test results. Direct Access Diagnostics surveyed only HIV-positive users from May 1996 through mid February 1997 and began to survey all users in February 1997. On June 26, 1997, the company announced the withdrawal of its product due to lack of demand, but continued to provide test results and administer the survey until August 19, 1997. Information on the total number of tests, test results, and sample adequacy was available for May 1996 to August 1997, but demographic and behavioral information comprises only those users who called from February 10 through August 29, 1997. Direct Access Diagnostics provided summary information aggregated by quarter and did not provide access to the call log.

From the National Center for HIV, STD, and TB Prevention, Centers for Disease Control and Prevention, Atlanta, Ga.

The mention of trade names, commercial products, or organizations does not imply endorsement by the US government.

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Toward Optimal Laboratory Use section editor, George D. Lundberg, MD, Editor, *JAMA*.

Table 1.—Home Collection Users, by Test Result, May 1996 Through September 1997*

| HIV Result | No. (%) of Tests | | No. (%) of Users Who Called for Results | |
|---|---|---|---|---|
| | DAD | HAHC | DAD | HAHC |
| Positive | 858 (0.9) | 636 (0.8) | 818 (95) | 610 (96) |
| Negative | 90 662 (94) | 73 011 (93) | 87 251 (96) | 71 263 (98) |
| Indeterminate† | 74 (0.07) | 1 (0.001) | 71 (96) | 1 (100) |
| Unsuitable sample | 4361 (0.05) | 4713 (0.06) | 4172 (96) | 4455 (95) |
| Total | 95 955 | 78 361 | 92 312 | 76 329 |

*HIV indicates human immunodeficiency virus; DAD, Direct Access Diagnostics; and HAHC, Home Access Health Corporation.
†For confirmation of repeatedly reactive immunoassays, DAD used Western blot assay and HAHC used immunofluorescence assay.

Table 2.—Characteristics of Persons Using Home Sample Collection HIV Tests*

| Category | All Users | HIV-Positive Users | HIV Prevalence |
|---|---|---|---|
| Sex | | | |
| Female | 39 | 15 | 0.4 |
| Male | 62 | 85 | 1.4 |
| Race | | | |
| African American | 5 | 16 | 2.7 |
| White | 85 | 69 | 0.7 |
| Hispanic | 8 | 12 | 2.6 |
| Other | 5 | 3 | 0.8 |
| Age, y | | | |
| 18-24 | 23 | 7 | 0.3 |
| 25-34 | 41 | 48 | 1.1 |
| 35-44 | 24 | 33 | 1.3 |
| 45-54 | 10 | 9 | 0.8 |
| ≥55 | 3 | 3 | 0.9 |
| Reported risk factor | | | |
| Heterosexual | 77 | 23 | 0.3 |
| Bisexual male† | 8 | 27 | 3.1 |
| MSM | 10 | 38 | 3.5 |
| IDU | 1 | 8 | 4.1 |
| MSM/IDU | 3 | 6 | 1.7 |

*Reported as percentage of total users who responded to demographic questions (N = 76 373 for sex; numbers slightly lower for other categories). HIV indicates human immunodeficiency virus; MSM, men who have sex with men; and IDU, injection drug use.
†From Home Access Health Corporation survey only. Direct Access Diagnostics did not survey this risk factor.

Table 3.—Testing History and HIV Test Result*

| Testing History | All Users, No. (%) | HIV-Positive Users, No. (%) |
|---|---|---|
| No previous test | 29 812 (58) | 224 (49) |
| Previous test | | |
| Negative | 21 292 (41) | 166 (34) |
| Indeterminate | 282 (0.5) | 8 (2) |
| Positive | 83 (0.2) | 57 (13) |
| Unknown | 218 (0.4) | 11 (2) |
| Total | 51 687 | 455 |

*Home Access Health Corporation surveyed users about their testing history, but Direct Access Diagnostics did not. HIV indicates human immunodeficiency virus.

Data in this analysis reflect the number of tests, not individual users, because HSC tests are anonymous, and it is impossible to ascertain if some users are repeat testers. No tests of statistical significance were performed for comparisons, because although all data available from HSC test users were included, there is little assurance that users who responded to the survey constitute a representative sample.

## RESULTS

Data were available for 174 316 tests, of which 95 955 (55%) were performed by DAD and 78 361 (45%) by HAHC (Table 1). Overall, 97% of users called for their results. A total of 165 194 specimens (95%) were suitable for testing; 9073 (5%) were not tested because they were contaminated, contained an insufficient amount of blood, or were submitted too long after they were obtained. The HIV prevalence among HSC test users was 0.9%.

Demographic and behavioral data were available from 76 373 persons (59%) who responded to at least 1 survey question: 70 620 HIV-negative, 865 HIV-positive, and 4888 persons who submitted samples unsuitable for testing. Response rates differed for the 2 HSC products and also for specific questions. Response rates averaged 67% among 78 361 HAHC users surveyed during pretest counseling. More users provided information on sex (70%) and age (68%) than ZIP code (51%). Response rates for all questions were higher (average, 76%) among HIV-positive HAHC users because counselors asked for further demographic information when giving test results and making referrals. Response rates for 49 712 DAD users, surveyed when they called for test results, averaged 43%. Like HAHC users, fewer DAD users provided ZIP code information, but response rates for HIV-positive and HIV-negative DAD users were similar. Because of higher response rates and the longer survey period, HAHC users account for approximately 72% of demographic and behavioral information. However, there were no significant differences in demographic or behavioral characteristics between HAHC and DAD users.

Tests were submitted from all 50 states, Washington, DC, Puerto Rico, and the US Virgin Islands. Most users were heterosexual; the largest percentages were men, white, and aged 25 to 34 years (Table 2). The HIV prevalence was highest among African Americans and Hispanics, those aged 35 to 44 years, men who have sex with men, and injection drug users. Although only 5% of users were African American and 5% Hispanic, they accounted for 16% and 12%, respectively, of positive results. Bisexual men constituted 8% of all users tested and 27% of positive results; this percentage may be even higher because the DAD survey did not distinguish bisexual men from other men who have sex with men. Considering data from only HAHC users, bisexual men accounted for 38% of the positive results.

Home Access Health Corporation asked users whether they had been tested previously for HIV and what they expected the test results to be. Overall, 59% of users reported they were testing for the first time (Table 3). The HIV prevalence was slightly higher (0.8%) among first-time testers than among users who had previously tested negative (0.7%). Of HIV-positive users, nearly half had never been tested before. Only 17% of those who tested positive for HIV had anticipated that their results would be positive, 46% expected their results to be negative, and 37% were uncertain. Among HAHC users found to be HIV negative, 2% had expected a positive test result.

Content analysis of the HAHC call log revealed that 65% of HIV-positive users who called to receive results accepted referrals for medical care and psychosocial services, 23% refused referrals because they had a source of follow-up care, and 12% were receiving antiretroviral therapy but had tested to see whether their HIV status had changed. During the telephone sessions, counselors noted that 21% of persons discussed notifying their partners, 8% asked the counselor to discuss the test result with their partner, and 5% disclosed that they already knew their partner was HIV positive. However, such information was not actively elicited from all callers.

The HAHC call log was also used to assess the psychological distress of HIV-positive users when they received their results. Information about coping was not systematically elicited from each user, but counselors recorded that 7% of the HIV-positive users expressed shock and dismay at an unexpected positive test result; 5% hung up immediately on receiving a positive test result, without counseling; and 3% asked someone else to call for their results (the counselor accommodated only after obtaining permission from the user). One of the 610 HIV-positive users expressed suicidal ideation; the counselor noted that this person was with a friend, who agreed to facilitate mental health support.

Of the 71 263 HIV-negative HAHC users who called for test results, 82% received the recorded message only, 29% called more than once to hear their test results and counseling, and 12% elected to speak with a counselor.

## COMMENT

Comparison of HSC test users with those tested at publicly funded HIV sites

suggests that HSC is used by persons who are at risk for HIV and those who do not seek other testing. The 0.9% HIV prevalence among HSC test users is nearly 3 times the estimated prevalence in the general population[2] and similar to that observed in 1996 at publicly funded clinics among persons tested for the first time (1.1%) and those whose previous result was negative (0.9%) (Centers for Disease Control and Prevention Client Record Data base, unpublished data, 1997). Although 58% of HSC test users and 44% of those tested at publicly funded sites were being tested for the first time, the proportion of HIV-positive HSC test users who had never been tested before (49%) is considerably higher than that (29%) at publicly funded sites. The high proportion (97%) of users who called for results compares favorably with publicly funded clinics, where the return rate in 1996 averaged 67%, ranging from 51% at sexually transmitted disease clinics to 83% at voluntary HIV counseling and testing sites.[4]

It is important to recognize the limitations of the data on user characteristics, as only 59% of users responded to questions about demographics and behavior. Because HSC testing is anonymous, no information is available about nonrespondents. This inability to characterize persons who may have used HSC testing hampers our understanding of the ultimate role of HSC in HIV testing strategies.

Two reviews[1,5] posed questions about home testing for which data now suggest some answers. The following 5 questions relate specifically to HSC and also to more general issues about consumer influence in the context of HIV testing.

1. *Do HSC tests expand access to testing?* Proponents argue that HSC tests encourage persons to be tested who might not otherwise. Evidence from this analysis supports this view: more than half of the users had not been tested previously. The data also show that HIV-infected bisexual males, African Americans, and Hispanics are using HSC tests, suggesting that it is an acceptable option for persons who may have less access to testing or who may be particularly concerned about confidentiality. Although relatively few African Americans and Hispanics used HSC tests, the risk for HIV seemed to be high among those who did. African Americans and Hispanics each accounted for 6% of HSC test users (compared with 30% and 18%, respectively, at publicly funded sites), but their HIV prevalence (2.7% and 2.6%, respectively) was similar to that for publicly funded test site users (2.6% and 2.0%).[3]

The overall effect of HSC tests on access to testing may be small. Excluding blood donors, an estimated 16.6 million HIV tests are performed annually in the United States.[4] Publicly funded clinics account for approximately 2.5 million (15%) of these tests and HSC accounts for approximately 200 000 (1%). Cost of the test ($30-$40) may present a barrier to the use of HSC. In a survey of 2370 HIV-negative persons in 9 states, 76% of respondents said they might use a free HSC test within the next year, but only 40% said they might use one if it cost $40.[6]

2. *Can consumers correctly use the HSC test?* Of specimens submitted by consumers, 5% were unsuitable for HIV testing, compared with 4.8% of dried-blood spot samples obtained by health professionals.[7] This suggests that consumers can obtain an adequate sample for testing. However, many persons are unwilling to provide finger-stick specimens,[8] which may limit the acceptability of HSC tests.

3. *Do HSC test users suffer because they receive no face-to-face counseling?* Opponents of HSC tests feared that telephone counseling would lead to emotional distress for persons who tested HIV positive and that many might commit suicide or fail to obtain follow-up medical care and psychological support. The evidence to date, based on small numbers of HIV-positive users, is mixed. In the first year of use, only 1 caller expressed suicidal ideation. More worrisome, 5% of callers who tested HIV positive hung up without counseling, and no follow-up information is available for them.

The data indicate that many HIV-positive HSC test users have a source of care and that those who do not are willing to accept referrals. Information is insufficient to determine whether HSC test users actually seek medical care or whether telephone counseling is effective for encouraging users to change their risk behaviors.

4. *How do HSC tests affect public health practices?* Concern about the effect of anonymous HSC testing on name reporting and partner notification led to attempts by several states to block the sale of HSC HIV tests, citing state laws that mandated the reporting of names of HIV-infected persons. However, under the federal Food, Drug, and Cosmetic Act, FDA approval of HSC tests preempted these more restrictive state laws.[9] No data yet exist on whether the availability of HSC tests hinders effective and timely surveillance or partner notification, but such information is also meager about other anonymous and private-sector testing. However, given the high proportion of users with sources of care or accepting referrals and the fact that health care professionals are required to report new cases, HSC tests are likely to improve these efforts: a high percentage of HIV-positive persons are learning of their HIV infection from HSC as their first test.

5. *What have we learned about evaluating consumer-use testing?* The course negotiated by the FDA during considerations of HSC testing offers some insight about whether the process for evaluating the safety and effectiveness of HSC tests will be useful for the introduction of other new technologies. The HSC tests were approved 10 years after the first product was submitted, during which the FDA grappled with its mandate to ensure the safety and effectiveness of home diagnostic products for HIV. For HSC tests, it seems to have been possible to collect sufficient data to evaluate safety and effectiveness of the device itself as well as the consequences of its approved use, such as the psychological responses of users. More detailed information also exists about the cost and feasibility of the data collection and postmarketing studies that were imposed on HSC product sponsors as conditions of approval. The approval of HSC tests for HIV may pave the way for the approval of other technologies, such as 1-step rapid HIV tests, which can provide results in 10 to 15 minutes without the need for a laboratory, and even true home tests,[10] which consumers could perform and interpret at home. These could dramatically change HIV testing, and HIV prevention strategies based on immediate access to test results could greatly affect the AIDS epidemic.

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TO: TODD SUMMERS
WHITE HOUSE NATIONAL OFFICE OF AIDS POLIC

FROM: MRL REFERENCE LAB MAKES
URINE HIV-1 TEST SYSTEM
AVAILABLE NATIONWIDE TODAY

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ATTN:

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TO: FAX PHONE#: 202-456-2438

DATE: Aug 12 1998

JOBID: 323920

4 pages including cover sheet

# MRL
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**URINE HIV-1 SCREENING AND CONFIRMATORY TEST PROCESSING NOW AVAILABLE THROUGH MAJOR REFERENCE LABORATORY**

**MRL Reference Laboratory to Process Calypte Urine Test System, Offering Health Care Professionals/Institutions Highly Accurate, Non-Invasive, Low-Risk Alternative to Blood Testing**

Cypress, CA -- August 12, 1998 -- MRL Reference Laboratory today announced that it has begun processing of the complete Human Immunodeficiency Virus Type 1 (HIV-1) urine test system for health care professionals and institutions. The test system, developed by Calypte Biomedical Corporation (NASDAQ: CALY), consists of the HIV-1 enzyme immunoassay (EIA) antibody screening test and the HIV-1 urine Western Blot confirmatory test, which detect the presence of antibodies to HIV-1 in urine samples.

In June, the U.S. Food and Drug Administration licensed the urine HIV-1 Western Blot test. The screening test had been licensed previously by the FDA. "Through clinical studies Calypte sponsored and through our own validation of the test system, we found Calypte's urine diagnostic test system to be a reliable alternative to serum testing," said MRL Director of Research and Development Dr. Wayne Hogrefe. "Studies show that in some instances, the urine test identifies HIV-infected individuals the serum test misses. Therefore, if people need to be absolutely certain of their HIV status, such as in transplant cases, it would be best to conduct both tests."

"Since the advent of HIV testing, MRL's clinical laboratory clientele have requested a non-invasive methodology for HIV testing," said Charlotte Perry, Global Product Manager for MRL. "The healthcare community needs to eliminate the limitations and risks inherent in serum sample collection and consequently increase the likelihood of a broader HIV screening effort in this country. MRL recognizes the immediate potential of a highly accurate HIV urine antibody test to meet these requirements."

MRL's clientele include other reference laboratories, medical centers, research laboratories, and pharmaceutical and biotechnology companies. In addition, MRL serves as the primary referral lab for the nations three largest national reference laboratories handling much of those labs' needs for emerging infectious and autoimmune diseases testing.

Perry stated that MRL expects the largest demand for its processing of the urine tests to come from its regional and national laboratory clients -- key sources to whom hospitals, physicians, HIV and STD clinics, and correctional facilities will turn for processing of the urine tests. She also said that MRL will process the urine tests for clients in Mexico and Latin America.

- more -

For both health care professionals and patients, urine testing offers important advantages compared to existing blood-based HIV tests. Those advantages include greater ease-of-use for health care workers, strong appeal to consumers and the lower cost of urine collection.

According to the National Institutes of Health Fact Sheet on HIV Infection and AIDS, there is no evidence that HIV is spread through urine, thereby significantly reducing risk of infection from collecting and handling specimens. Urine testing eliminates accidental needle sticks and other exposure-related dangers, thus protecting both health care workers and patients.

In addition to the benefits the test offers to the health care system, the urine test system is expected to appeal to many Americans who have avoided being tested in the past because they dislike having their blood drawn. A survey of approximately 1,000 Americans conducted by Market Facts, Inc., showed that one of every two respondents would prefer a urine HIV test over a blood test. Of those respondents, 80 percent cited a fear of needles as their reason for preferring the urine test. There are approximately 60 million HIV tests performed in the United States in 1997.

"We're very excited that MRL Reference Laboratory has adopted the urine test system," said Bill Boeger, chairman and CEO, Calypte Biomedical. "This represents another avenue for health care professionals and institutions, and, of course, for those interested in getting tested through a non-invasive and accurate means, to be able to use the urine test. The more ways we can make easy, painless testing available, the more people will come forward to be tested. As recent studies have concluded, the sooner HIV-positive individuals begin antiviral therapy, the greater their chances of extending their lives."

While the screening and confirmatory tests can be processed in a standard lab, health care institutions and professionals will now be able to use the HIV urine test if they do not have a laboratory, or if they do not wish to dedicate the resources necessary to process the tests. MRL's processing/turn-around times for the screening and confirmatory tests are one and two to three business days, respectively.

To determine the specificity of the urine Western blot, clinical trials were conducted on a low-risk population. Blood serum and urine samples were tested and results compared. The results showed that the specificity for this population was 100 percent (515 out of 515).

To determine the sensitivity of the urine Western blot, clinical trials were conducted on persons known to be HIV-1 antibody positive by blood tests. Serum and urine samples were tested and results compared. The results showed that the sensitivity of the urine Western blot was 99.7 percent (746 out of 748). The two samples that were urine Western blot negative were from seropositive individuals who had already been diagnosed with AIDS and were on anti-retroviral therapy.

In addition, a study published in the November 1997 issue of *Nature Medicine* revealed that a combination of urine- and blood-based tests detected HIV-1 antibodies with greater sensitivity than can be achieved by either test alone.

Like most blood tests, the urine HIV-1 screening test and the urine HIV-1 confirmatory test do not detect the actual HIV virus, but the antibodies produced by the body after exposure to the virus.

In the United States, Seradyn, Inc., of Indianapolis will market both the urine HIV-1 screening and confirmatory tests. Seradyn sells the screening test under the trade name Sentinel. Cambridge Biotech Corporation manufactures the new urine-based confirmatory test under license from Calypte.

* * *

Statements in this press release that are not historical facts are forward-looking statements, including statements regarding market adoption of the HIV-1 urine testing system. Actual results may differ materially from the above forward-looking statements due to a number of important factors, and will be independent upon the company's ability, directly or through third parties, to successfully manufacture and market the HIV-1 urine testing system. Factors which may impact the company's success are more fully discussed in the company's most recent quarterly report on forms 10-Q and 10-K.

*For more information on how to purchase or evaluate the product, please call John Innocenti of Seradyn at 800-428-4007 (x2957), or Dick Van Maanen of Calypte at 510-749-5100. For information on sending specimens for testing, please call Charlotte Perry of MRL Reference Laboratory at 800-445-0185 (x139).*