

Outcomes of Offering Rapid Point-of-Care HIV Testing in A Sexually Transmitted Disease Clinic

Sabrina R. Kendrick, MD,*†‡ Karen A. Kroc, BS,* David Withum, DrPH, DTMH,§
Robert J. Rydman, PhD,†|| Bernard M. Branson, MD,§ and Robert A. Weinstein, MD*†‡

Background: Delays in receipt of positive HIV test results and in entry into HIV care are common problems in clinics; in public venues, up to 33% of patients with negative results and 25% of those with positive results never learn their results.

Methods: Patients aged 18 years or older at an urban sexually transmitted disease (STD) clinic were offered rapid HIV testing between October 1999 and August 2000. Specimens were tested using the rapid Single Use Diagnostic System for HIV-1 (SUDS; Abbott/Murex, Norcross, GA), and results were confirmed by conventional enzyme immunoassay and Western blot (WB) analysis. Trained health educators performed all HIV counseling, phlebotomy, and rapid testing.

Results: Of 1977 eligible patients, 1581 (80%) agreed to HIV testing; of these, 1372 (87%) accepted rapid testing and 1357 (99%) received same-visit results and posttest counseling. Thirty-seven (2.7%) were HIV-positive as confirmed by WB analysis. One of these HIV-positive participants died, but the remaining 36 went to their first clinic appointment.

Conclusion: Rapid HIV testing was acceptable and feasible in this STD clinic and facilitated entry of newly identified HIV-infected patients into health care.

Key Words: counseling and testing, HIV, HIV testing, rapid HIV testing, sexually transmitted disease clinic

(*J Acquir Immune Defic Syndr* 2005;38:142–146)

Approximately 40,000 persons in the United States become infected with HIV each year. In 2001, the Centers for Disease Control and Prevention (CDC) developed an HIV prevention strategic plan to reduce by 50% the number of new

infections by 2005. Key goals in the CDC plan are to increase, through voluntary counseling and testing, the proportion of persons who know that they are infected from the current 70% to 95% and to increase the proportion of HIV-infected persons who are linked to appropriate prevention, care, and treatment from the currently estimated 50% to 80%.¹ These goals may be difficult for several reasons, including the current 2-visit system for HIV counseling and testing, in which approximately one third of persons with positive test results do not return to receive them.²

The use of rapid tests that provide results within 15 to 60 minutes should increase the percentage of people who learn their HIV infection status.³ Numerous rapid HIV tests have been described since the late 1980s.^{4–16} Several studies showed rapid testing to be acceptable to patients and to offer a realistic way to increase the number of persons who are tested and learn their serostatus.^{2,3,17–20} The use of sustained point-of-care rapid testing has not been fully explored, however, and it is not known whether rapid testing promotes more timely entry into care. We therefore conducted a study to determine the feasibility and acceptability of point-of-care rapid HIV testing and its effects on receipt of test results and subsequent entry into care by persons newly identified with HIV.

METHODS

A 10-month descriptive study was conducted in the sexually transmitted disease (STD) clinic of the Ruth M. Rothstein CORE Center, an outpatient infectious disease center located on the west side of Chicago 2 blocks from Cook County Hospital. During 1999 through 2000, 3500 HIV-infected individuals received primary care at the CORE Center, where all services are available regardless of the patient's ability to pay.

The walk-in STD clinic operates Monday through Friday from 9:00 AM to 8:00 PM and provides HIV counseling and testing. Of the 16 sites on the Cook County medical campus reporting gonorrhea and *Chlamydia*, 29% and 16% of cases, respectively, were reported from the CORE Center STD clinic in 1999 through 2000. The STD clinic accounts for nearly one quarter of the reactive syphilis reports from the medical campus. In 1999, two thirds of the patients seen in the STD clinic were tested for HIV. Individuals with newly identified HIV infection are referred to medical and social services within the CORE Center.

From October 1999 to August 2000, participants were recruited from among patients seeking care at the STD clinic

Received for publication March 8, 2004; accepted June 16, 2004.

From the *Department of Medicine, The Ruth M. Rothstein CORE Center, Chicago, IL; †Department of Emergency Medicine, Cook County Hospital, Chicago, IL; ‡Department of Medicine, Rush Medical College, Chicago, IL; and §National Center for HIV, STD, and TB Prevention, Centers for Disease Control and Prevention, Atlanta, GA.

||Deceased.

Supported by cooperative agreement CCU516455 from the Centers for Disease Control and Prevention.

Reprints: Robert A. Weinstein, Division of Infectious Diseases, John Stroger Hospital of Cook County, 129 Durand Building, 1901 West Harrison Street, Chicago, IL 60612 (e-mail: rweinste@rush.edu).

Copyright © 2005 by Lippincott Williams & Wilkins

Monday through Friday from 9:00 AM to 5:00 PM. The clinic nurse referred patients to the study health educators after medical triage. Three health educators with training and experience in the laboratory and HIV counseling offered all eligible patients a rapid HIV test, provided pretest and posttest counseling, collected blood, and performed the rapid test. Patients who declined the study or were ineligible could still elect to receive standard HIV testing.

Patients were eligible if they were aged 18 years or older, spoke English or Spanish, were not known to be HIV infected, had not been tested for HIV within 3 months, and had not come to the clinic just to receive laboratory results. Patients were ineligible if the health educator perceived that they did not fully comprehend HIV infection and the testing process (ie, mentally incapable or comprehension affected by substance use) or if they expressed discomfort or inappropriate responses during pretest counseling when discussing the receipt of same-day HIV test results.

Counseling scripts were developed to inform the participants of their rapid HIV test results based on CDC recommendations.²¹ The study was approved by the Institutional Review Boards of the Cook County Hospital and CDC, and all participants provided written informed consent.

The established patient flow in the STD clinic was to direct patients to the provider before HIV pretest counseling or phlebotomy was performed. During the study, the clinic flow was redirected, enabling study staff to offer HIV testing and study participation earlier in the patient visit. This allowed HIV testing to be performed and results to be reported to the participant and provider before completion of the visit.

Two 7-mL blood specimens were collected by venipuncture from each participant. While participants received their medical care in the clinic, a health educator performed the Single Use Diagnostic System for HIV-1 (SUDS; Abbott/Murex, Norcross, GA) test on 1 of the specimens according to the manufacturer's instructions. Our health educators had previous laboratory experience and were readily trained to perform the moderately complex SUDS test. Specimens were tested individually or in batches of up to 5 samples; positive and negative controls were run with each test or batch. Reactive SUDS tests were immediately repeated in duplicate, and the final result was determined by concordance on at least 2 of the 3 tests.

The second specimen from each participant was sent to the hospital's Virology Laboratory for an enzyme immunoassay (HIV antibody HIV-1/HIV-2 EIA; Abbott Laboratories, Abbott Park, IL). Specimens with repeatedly reactive EIA results were tested using Western blot (WB) analysis (Nova-path HIV-1 Immunoblot; Bio-Rad Laboratories, Hercules, CA). All specimens with reactive SUDS test results were tested using WB analysis even if the EIA results were negative. EIA and WB results were used as the standard for calculating sensitivity, specificity, and predictive values for SUDS.

Rapid test results were available before participants were discharged from the clinic. Those with negative results received their results during a brief session and were told to return in 2 weeks to receive their standard test results. Those with positive SUDS results received posttest counseling

according to scripts based on CDC recommendations.²¹ This counseling included a discussion of the preliminary positive result and risk reduction behaviors. These participants were given an appointment for medical evaluation in the HIV primary care clinic within 2 weeks (when WB results would be available). Study staff contacted participants with discordant results and scheduled an appointment for repeat testing. For continuity, the health educator who counseled the participant on the original visit was responsible for this follow-up.

Participants scheduled to return to the clinic as a result of study participation were given a \$10 food voucher at the return visit to offset transportation costs. The participants had no knowledge of the voucher before receipt. Health educators attempted to contact and reschedule any HIV-positive participant who failed to keep or reschedule a primary care clinic appointment. Outreach field investigation was initiated for those HIV-positive participants who could not be reached by telephone or mail.

For each participant, the duration of counseling, testing, and waiting and the total time to receipt of test results were tracked. To ascertain entry into and retention in HIV care, computer records and medical charts at the CORE Center were reviewed. Retention in care was defined as 2 or more visits within 6 months of receiving the positive HIV test results. When available, CD4 and viral load results from initial clinic visits were collected from computer records.

The STD clinic database was reviewed retrospectively to identify patients seen in the clinic during this same interval who received standard rather than rapid HIV testing and were newly identified with HIV infection. Data on receipt of results and entry into care were collected on these patients for comparison with those who received rapid testing.

Data were analyzed using PC SAS Version 8e (SAS Institute, Cary, NC).

RESULTS

During the 10-month study period, more than 6500 patients visited the STD clinic. Of the 4462 who visited during study hours, 2641 (58%) were referred to study health educators. The percent referred increased from approximately 40% during the first 4 study months to 80% by the end of the study.

Of 1977 patients eligible for the study, 1581 (80%) agreed to HIV testing: 1372 (87%) accepted rapid HIV testing, and 209 (13%) accepted conventional HIV testing. Patients who accepted conventional but not rapid HIV testing stated that they did not have time to wait for results (57%), thought that they were not ready to receive same-day results (28%), or gave other reasons (eg, did not want to be involved in research) or no reasons (15%). Patients who refused all HIV testing (rapid and conventional) were not asked for a reason. Demographic data for eligible patients approached are summarized in Table 1.

Among the 664 (25%) ineligible patients, 235 (35%) had been HIV tested within 3 months; 144 (22%) were known to be HIV infected; 129 (19%) were at the clinic to receive test results only; and 156 (24%) were younger than 18 years, unable to provide informed consent, identified as ineligible by

TABLE 1. Demographic Characteristics of Eligible Patients

	Accepted Rapid HIV Test N = 1372	Accepted Rapid Test, HIV-Positive Results N = 37	Refused Rapid Test but Accepted Standard HIV Test N = 209	Refused All HIV Testing N = 396
Age (y)	n (%)	n (%)	n (%)*	n (%)
18–24	565 (41)	2 (5)	73 (35)	143 (36)
25–29	195 (14)	4 (11)	32 (15)	77 (19)
30–39	340 (25)	21 (57)	42 (20)	98 (25)
40–49	212 (16)	7 (19)	45 (22)	52 (13)
50+	60 (4)	3 (8)	16 (8)	26 (7)
Gender				
Male	878 (64)	26 (70)	132 (63)	244 (62)
Female	494 (36)	11 (30)	76 (37)	152 (38)
Race				
Black	1014 (74)	26 (70)	141 (68)	332 (84)
White	133 (10)	1 (3)	15 (7)	18 (5)
Hispanic	169 (12)	7 (19)	44 (21)	32 (8)
Other	56 (4)	3 (8)	8 (4)	14 (3)

*Demographic data missing for 1 patient.

the health educator during pretest counseling, or unavailable for follow-up.

Of the 1372 participants, reactive SUDS results were confirmed by WB analysis for 37 (2.7%). SUDS results from 7 participants differed from the EIA and WB results: 6 were false positive and 1 was false negative. SUDS sensitivity was 97.4% (95% confidence interval (CI): 96.6–98.2), specificity was 99.6% (95% CI: 99.3–99.9), positive predictive value was 86% (95% CI: 84.2–87.8), and negative predictive value was 99.9% (95% CI: 99.7–100). Another blood sample was obtained from these 7 participants within 2 weeks, and 5 of 7 reported for retesting within 48 hours of being contacted by the health educator. Retesting using EIA and WB analysis produced the same outcome; however, retesting using SUDS produced a reactive result for the participant whose first result was false negative.

The immediate response of the health educators to our first false-positive result (after 3 months, 227 tests, and 7 confirmed positive tests) was disbelief and loss of confidence in SUDS. Intellectually, they understood the limitations of the test, and after convening with colleagues to discuss their doubts and concerns, they confidently contacted those patients and quickly brought them in for repeat testing. The patients actually dealt well with their discordant results, as evidenced by their quick and uneventful responses to our request for retesting. Those who tested false positive were relieved to learn the rapid test result was in error, although we are aware of 1 patient who chose conventional over rapid testing on a future clinic visit. The patient with a false-negative rapid result stated that he was not surprised that he was HIV infected because he had self-reported high-risk behavior.

The mean elapsed time between the start of pretest counseling and completion of the posttest session was 70 minutes for participants whose SUDS results were negative

and 96 minutes for participants whose SUDS results were positive. Specimens with reactive SUDS results required additional time for repeat testing, and participants with positive SUDS results received longer posttest counseling (mean = 18 minutes) than did participants with negative SUDS results (mean = 2 minutes). Before leaving the clinic, 1357 (99%) participants received their rapid test results (negative or preliminary positive).

All 37 HIV-positive participants identified using rapid testing (and the 6 participants with false-positive preliminary results) received their preliminary positive results and posttest counseling on the day of testing. Self-reported risk factor information during pretest counseling for these 37 participants was as follows (risks not mutually exclusive): 15 (41%) men who have sex with men (MSM), 12 (32%) sexual contact with a partner who had HIV/AIDS (6 heterosexuals and 6 MSM), 12 (32%) heterosexuals with no identified risk factors, 3 (8%) injection drug use (IDU) or sex partner with a history of IDU, and 1 (3%) lesbian with no identified risk factors.

One participant died as a result of HIV-related complications before the first primary care clinic appointment; the remaining 36 participants reported for their first appointment in a median of 10 (range: 2–84) days. Of these, most (29) kept their clinic appointment without additional staff intervention, and 7 missed their first clinic appointment but were successfully contacted to reschedule. Of the 36 who entered into care, 30 (83%) remained in care. Their median initial CD4 count was 283 (range: 1–1643) cells/mm³, and their median viral load at the initial visit was 53,259 (range: <50–500,000) copies/mL; 20 (67%) met the current recommendations for antiretroviral therapy and were prescribed medication.

Of the 19 (1.9%) clinic patients newly identified with HIV infection by the standard test method during this same period, 84% received their results in a posttest counseling session 2 weeks after initial testing and entered into care in a median of 31 days after testing; 68% were retained in care. Receipt of results and entry into care could not be verified for 16% of these patients.

CONCLUSIONS

In this STD clinic, rapid HIV testing provided 99% of participants, and 100% of HIV-positive participants, with same-visit results and led to timely entry into care for those with positive HIV test results. Our findings that most participants (87%) accepted rapid rather than conventional testing and were willing to wait, when necessary, to receive test results and posttest counseling indicate that rapid HIV testing is acceptable to patients. Other studies of rapid HIV testing in the United States have found that the percentage of patients leaving before receiving their test results ranged from 1% to 73% (Table 2). Del Rio et al¹⁸ found that most patients tested with SUDS in their study did not receive same-day results. Factors that contributed to this outcome included the need to wait for a phlebotomist for blood collection and performance of the SUDS test, because of its moderate complexity, in the hospital laboratory rather than on-site in the clinic. In the study of rapid testing of emergency department patients by Kelen et al,¹⁹ only 55% of the HIV-positive patients kept their first

TABLE 2. Summary of Rapid HIV Test Studies in Adult US Populations

Reference	Site	Study Period	Rapid Test Used	Patients Tested	Rapid Result Received by Patient	% Patients Who Received Results	Entry Into Care	Comment
17	STD clinic AT clinic	October 19, 1993–June 30, 1993	SUDS HIV-1	1923*	No	Not applicable	Not evaluated	Laboratory-based evaluation of test performance done on consecutive specimens from 2 sites
20	ER and hospital (admitted patients)	1992–1994	Genie HIV1/2	246 ER 591 hospital (admitted patients)	No No	Not applicable	Not evaluated	Rapid test performed in real time, but results of rapid test not given to patients
3	STD clinic, AT clinic	July 6, 1993–October 1, 1993	SUDS HIV-1	1493 STD 984 AT clinic	Yes Yes	93% STD 99% AT clinic	Not evaluated	On-site rapid testing feasible and preferred by clients
19	ER	1993–1995 (40 wks distributed over 3 phases)	SUDS HIV-1	467 (phase 2+3)	Yes (phase 2+3)	74% (phase 2+3)	55% (phase 2+3)	Phase 1 = 20 weeks, conventional test only Phase 2 = 10 weeks, choice of rapid or conventional test Phase 3 = 10 weeks, rapid test performed in hospital versus ER laboratory
18	Outpatient clinic	March 20, 2000– September 1, 2000	SUDS HIV-1	886	Yes	27%	See comments	Unable to determine entry to care for rapid test only: 55 of 74 new HIV ⁺ clients learned results, and 26 of 55 entered care
Current study	STD clinic	October 18, 1999–August 8, 2000	SUDS HIV-1	1372	Yes	99%	83%	SUDS performed as point-of-care test, provide SUDS results to patients before they complete their medical visit

*Number of specimens tested.
AT indicates anonymous test; ER, emergency room.

scheduled HIV clinic appointment. In our study, a much higher proportion received their results and entered into care (see Table 2).

Key elements that contributed to our high rates of receipt of test results, compared with previous studies, were the modified patient flow in the STD clinic to permit phlebotomy early in the patient visit, the use of SUDS as a point-of-care test, and assignment of staff dedicated to performing the test. The clinic staff adapted willingly and relatively easily to the change in clinic flow, in part, because they found the timely results to be useful. For example, knowledge of positive SUDS results for 3 patients with symptomatic complaints resulted in their prompt hospitalization.

Point-of-care use of SUDS was facilitated in our study, as in previous reports,¹⁹ by designating an on-site area for processing specimens, performing the tests, and completing the paperwork. The number of tests performed suggests that it was logistically feasible for our trained staff to complete the

SUDS test as a point-of-care procedure in our STD clinic, although SUDS is categorized as a moderately complex test under the Clinical Laboratories Improvement Amendments (CLIA).²² The availability of a rapid test more suitable for true point-of-care use (eg, the recently Food and Drug Administration [FDA]–approved OraQuick Rapid HIV-1 Antibody Test; Ora-Sure Technologies, Bethlehem, PA) should enable others to achieve even better results. Although the performance (especially positive predictive value) of the new-generation rapid tests clearly exceeds that of SUDS, users of rapid technology must still be prepared to address discordant results. We attribute the quick and uneventful responses of our patients with discordant results, when contacted by the health educators, to several factors, including a discussion of the possibility of discordant results and of the urgency of repeat testing during counseling, accurate assessment of the patients’ capability to accept rapid test results, and the rapport established between the health educator and patient.

Our experience suggests additional operational components that may affect the effectiveness of rapid HIV testing programs. The high proportion of patients who kept their first HIV clinic visit appointment as scheduled may have resulted from our practice of scheduling these appointments when preliminary positive SUDS test results were given to the patient, at which time, a sense of importance and urgency about linkage to care could be created. This may also account for the differences noted between newly identified HIV-infected patients tested by the rapid versus standard method who entered into and were retained in care. Similarly, the sense of immediacy associated with rapid test technology might encourage and facilitate partner notification for counseling and testing. This warrants further investigation.

The consensus in public health and medical communities is that individuals with HIV should be identified as early as possible to prevent disease progression (secondary prevention).²³ Although several HIV-positive participants had CD4 counts and viral loads consistent with early infection and, according to the current guidelines for treatment,²⁴ might wait to begin antiretroviral therapy, most of the HIV-positive participants identified by SUDS testing were at a stage of immuno-compromise at which highly active antiretroviral therapy is recommended.

The findings in this study and their general applicability are subject to several logistic and methodologic limitations. First, despite the ability to do SUDS point-of-care testing, the complexity of the test did affect the time that the health educators were available to screen and counsel all potential participants during study hours. Second, study health educators were dependent on rotating clinic nursing staff to refer participants after triage. Despite this dependence, by the end of the study, 80% of patients were being referred to the study. Third, although we used dedicated staff because of the technologic constraints of the SUDS test, new products allow rapid testing without additional staff. Finally, the study was observational, and participants were not randomly selected; nevertheless, the findings are striking compared even with other studies on the use of rapid HIV tests (see Table 2).

In conclusion, our findings show that rapid HIV testing is acceptable and feasible in a high-volume STD clinic and that rapid HIV testing facilitated entry into care. SUDS is being succeeded by a new generation of rapid HIV tests that return results more quickly with fewer logistic constraints. It is important now to compare testing venues (eg, STD clinics, other outpatient areas, emergency departments) to determine sites where rapid HIV testing will be most effective at increasing knowledge of HIV serostatus and promoting earlier identification of and entry into care for HIV-infected persons.

ACKNOWLEDGMENTS

The authors thank Linda Mezny and Tony Mazza for their support in the Virology Laboratory, Harold Jaffe for critical review and valuable discussion of the manuscript, Leticia Sanchez for administrative support, and the staff at the CORE center for the care provided to our patients.

REFERENCES

- Centers for Disease Control and Prevention. *HIV Prevention Strategic Plan Through 2005*. Atlanta: US Department of Health and Human Services, Centers for Disease Control and Prevention; 2001.
- Centers for Disease Control and Prevention. Advancing HIV prevention: new strategies for a changing epidemic—United States, 2003. *MMWR Morb Mortal Wkly Rep*. 2003;52:329–332.
- Kassler WJ, Dillon BA, Haley C, et al. On-site, rapid HIV testing with same-day results and counseling. *AIDS*. 1997;11:1045–1051.
- Carlson JR, Mertens SC, Yee JL, et al. Rapid, easy, and economical screening test for antibodies to human immunodeficiency virus. *Lancet*. 1987;1:361–362.
- Nara PL, Hatch WC, Dunlop NM, et al. Simple rapid, quantitative, syncytium-forming microassay for the detection of human immunodeficiency virus neutralizing antibody. *AIDS Res Hum Retroviruses*. 1987;3:283–302.
- Langlois AJ, Matthews TJ, Weinhold KJ, et al. Detection of HIV-1 neutralizing antibodies by a simple, rapid, colorimetric assay. *AIDS Res Hum Retroviruses*. 1988;4:63–69.
- Watson-Williams EJ, Yee JL, Carlson JR, et al. Solid phase red cell adherence immunoassay for anti-HIV 1: a simple, rapid, and accurate method for donor screening. *Transfusion*. 1988;28:184–186.
- Van de Perre P, Nzaramba D, Allen S, et al. Comparison of six serological assays for human immunodeficiency virus antibody detection in developing countries. *J Clin Microbiol*. 1988;26:552–556.
- Quinn TC, Riggan CH, Kline RL, et al. Rapid latex agglutination assay using recombinant envelope polypeptide for the detection of antibody to the HIV. *JAMA*. 1988;260:510–513.
- Kemp BE, Rylatt DB, Bundesen PG, et al. Autologous red cell agglutination assay for HIV-1 antibodies: simplified test with whole blood. *Science*. 1988;241:1352–1354.
- Schwartz O, Henin Y, Marechal V, et al. A rapid and simple colorimetric test for the study of anti-HIV agents. *AIDS Res Hum Retroviruses*. 1988;4:441–448.
- Spielberg F, Kabeya CM, Ryder RW, et al. Field testing and comparative evaluation of rapid, visually read screening assays for antibody to human immunodeficiency virus. *Lancet*. 1989;46:135–140.
- Barbara JA, Salker R, Challis P, et al. Gelatin particle agglutination assay for HIV antibodies: a rapid, economical modification with increased sensitivity. *Med Lab Sci*. 1989;46:135–140.
- Osther K, Klintmalm G. The quick Western blot, a novel transportable 50-minute HIV-1 antibody test. Application in organ procurement for transplantation. *Transplantation*. 1989;47:834–838.
- Constantine NT, Fox E, Abbatte EA, et al. Diagnostic usefulness of five screening assays for HIV in an East African city where prevalence of infection is low. *AIDS*. 1989;3:313–317.
- Xu JY, Gorny MK, Zolla-Pazner S. An immuno-dot blot assay for the detection of antibody to HIV. *J Immunol Methods*. 1989;120:179–183.
- Kassler WJ, Haley C, Jones WK, et al. Performance of a rapid, on-site human immunodeficiency virus antibody assay in a public health setting. *J Clin Microbiol*. 1995;33:2899–2902.
- Centers for Disease Control and Prevention. Routinely recommended HIV testing at an urban urgent-care clinic—Atlanta, Georgia, 2000. *MMWR Morb Mortal Wkly Rep*. 2001;50:538–541.
- Kelen GD, Shahan JB, Quinn TC, et al. Emergency department-based HIV screening and counseling: experience with rapid and standard serologic testing. *Ann Emerg Med*. 1999;33:147–155.
- Irwin K, Olivo N, Schable CA, et al. Performance characteristics of a rapid HIV antibody assay in a hospital with a high prevalence of HIV infection. *Ann Intern Med*. 1996;125:471–475.
- Centers for Disease Control and Prevention. Rapid HIV tests: issues for counselors providing HIV prevention counseling, March 1998. Available at: <http://www.cdc.gov/hiv/pubs/rt/rapidct.htm>. Accessed March 1, 1999.
- Centers for Medicare and Medicaid Services. CLIA Program, clinical laboratory improvement amendments. Available at: <http://www.cms.hhs.gov/clia>. Accessed May 21, 2004.
- Levi J. An HIV agenda for the new administration. *Am J Public Health*. 2001;91:1015.
- Department of Health and Human Services and the Henry J. Kaiser Family Foundation. Guidelines for the use of antiretroviral agents in HIV-infected adults and adolescents, February 4, 2002. Available at: <http://www.hivatis.org>. Accessed November 3, 2003.