

Home Access HIV-1 Test System
Summary of Safety and Effectiveness

I. General Information:

- A. The Generic Product Name: Home Access™ HIV-1 Test System
- B. The Trade Names: Home Access™
Home Access™ Express
- C. Applicant's Name and Address: Home Access Health Corporation
W. Hassell Road, Suite 1510
Hoffman Estates, IL 60195-5200
- D. PMA Reference Number: #BP950002
- E. Date of Panel Recommendation: June 22, 1994
- F. Date of Notice Approval: July 22, 1996

II. Indications for Use

The Home Access Express HIV-1 Test System is intended for the purpose of anonymous HIV-1 testing for self-use by the adult population, eighteen years or older, who have no training or experience in drawing blood specimens. The system is intended to provide education about HIV infection and risk reduction and to offer counseling, medical/psychosocial referrals, and assistance in partner notification.

III. Device Description

Four major interactive components form the HAHC testing service: 1) Home Access HIV-1 Home Collection Kit; 2) CLIENTtrak™ (Interactive Voice Response System [IVRS]; Automated HIV/AIDS Educational Announcement; and client database; 3) laboratory testing; and, 4) counseling and referral services.

The specimen collection kit contains the materials necessary to collect blood specimens in the privacy of the home and to ship the specimens to a qualified testing laboratory. Each Home Access HIV-1 Home Collection Kit contains the following: instructional manual and HIV/AIDS educational booklet in English and Spanish, blood spot collection card pre-coded with a unique 11-digit Home Access Code Number (HACN), two safety lancets, alcohol wipe, sterile gauze pad, bandage, foil return pouch containing a desiccant, safety lancet disposal container, shipping container, and pre-addressed, prepaid return envelope.

The specimen envelopes are placed in the pre-addressed, prepaid return envelope. The Home AccessSM Express return envelope can then be dropped off at the express carrier collection point, or Home AccessSM return envelope placed in a mail box, depending on the product chosen by the user.

The testing procedure begins when the client reads the instructional booklet and the educational booklet (English and Spanish) provided with the kit. The instructions require the client to call a toll-free number to register the unique 11-digit number (HACN) provided in the test kit. A subset of data, supplied voluntarily by the client, is collected and transferred to the CLIENTtrakTM database. Bilingual English/Spanish counselors and IVRS are available as required for Spanish-speaking clients.

Specifically, the client is asked to provide basic demographic data (year of birth, sex, race, and zip code), a history of prior HIV antibody testing, knowledge of prior test results, expected result from the current test, and risk factors for HIV infection. The client then listens to an automated, 5-minute educational session about the HIV-1 antibody test, HIV prevention, risk reduction behavior, and AIDS. Throughout the education session, clients have the option of speaking with an HAHC counselor or physician to discuss any questions or concerns. In addition, the toll-free number, operational 24 hours a day, 7 days a week, except holidays, gives clients access to counselors at all times before and after sample collection.

Test results are available to the client 3 business days for the Home Access Express Kit and about 7 days for the Home Access Kit after he/she ships the specimen to the testing laboratory. To retrieve results, the client again calls the toll-free number and provides his/her 11-digit Home Access Code Number (HACN). Clients who have not completed the pretest registration do so at this time.

All samples are shipped to the laboratory meeting CLIA requirements and complying to the Food and Drug Administration's Good Manufacturing Practices. The testing of specimens occurs in a dedicated laboratory where all testing processes and procedures are performed in accordance with written standard operating procedures. As per the GMPs, laboratory equipment and the Information Systems system have been formally validated. All employees are required to undergo GMP training and proficiency training.

Blood spot samples received by the lab are evaluated for adequacy (quantity and quality) of the specimen; samples are punched, eluted, and tested according to Organon Teknika Corporation Vironostika HIV-1 enzyme immunoassay (EIA) licensed protocol, or the Genetic Systems LAV EIA HIV-1 EIA, at the direction of HAHC. The Waldheim Pharmazeutika Fluorognost Immunofluorescent HIV-1 Antibody (IFA) test is performed on all repeatedly EIA reactive blood spot samples. Results are retrieved from the laboratory's computer system twice a day and imported into the CLIENTtrak™ database. Test results are available to the client (as described previously) through HAHC, within 3 business days for the Express Kit and 7 days for the Standard Kit after shipment of the sample to the laboratory.

HAHC provides clients access to their test results by telephone in one of two ways: through an interactive voice response system (IVRS) or directly from a counselor. Clients whose sample tested HIV-1 EIA negative or EIA repeatedly reactive and IFA negative will be advised that their sample tested "negative." Clients with negative test results and clients who submitted an insufficient quantity of blood for testing may retrieve their results directly from the CLIENTtrak™ database through the IVRS; these clients can also speak with a counselor if they choose. Clients whose sample tested HIV-1 EIA repeatedly reactive and IFA indeterminate will be advised their results are "indeterminate," and clients whose sample tested HIV-1 EIA repeatedly reactive and IFA positive will be told their results are "positive." All clients with indeterminate or positive results will receive results directly from a counselor. Clients submitting samples which are not of sufficient quantity or quality will be told their samples were "insufficient" and not tested.

A pre-determined percentage of all clients with negative results are forwarded directly to a counselor. All other test results are reviewed and released to the counseling staff by the HAHC medical director, who provides guidance to the counselor in a patient-notes field on the CLIENTtrak™ database; the counselor then informs the client. In the case of positive results, the counselor provides both the results and referrals to dedicated clinics and/or physicians in the client's local vicinity, and information about partner notification services. The counselors recommend retesting for clients whose specimens are not tested or who have indeterminate results.

Negative results will be available to clients through the IVRS for 30 days after the system is accessed. Positive results are available on-line for up to 1 year and thereafter are archived indefinitely and are accessible by the medical director if needed. Clients with negative results may speak with a counselor as often as three times in a 30 day period after their results become available. Clients with positive results may speak with a counselor 6 times over 12 months after their results become available.

At the time of providing a client positive results, the counselor will evaluate the coping skills, availability of personal support networks, and ability to inform sexual/needle-sharing partners. If necessary, advice on partner notification will be provided; and if requested, clients will be

referred to their local public health services for help in notification. Clients with positive results are referred to physicians or clinics within their geographic location (based on client-entered zip code). Each client requiring referral is provided at least one individually qualified by HAHC personnel. Clients are also provided with referrals to the National AIDS Hotline and other psychosocial services if they wish.

IV. Warnings and Limitations of Use

- A. Samples that are insufficient in size or quality will not be tested by the laboratory.
- B. Validation of performance characteristics for use in those under the age of 18 has not been performed.
- C. The HIV-1 Test System is not recommended for use by hemophiliacs or for those on anticoagulant therapy, unless a physician is consulted.

V. Alternate Practices and Procedures

A. Utilization of Current HIV Testing Services

It is estimated that 1 million people in the United States (1 of every 250 people) are infected with HIV-1¹ (World Health Organization), at least 40% of whom have never been tested.² The Home Access HIV-1 System is designed to detect HIV-1 infection in previously undiagnosed individuals who have not taken advantage of current testing services for any of several reasons, including fear of test outcome, fear of discrimination, potential loss of insurance benefits, inability or unwillingness to go to a state public health clinic for testing or to receive results and counseling, and the negative social stigma and psychological implications associated with the label of AIDS.³ Furthermore, reporting of newly diagnosed seropositives may be required to public health officials. Thus lack of anonymity can be deterrent to more widespread testing for HIV-1 infection.

On the basis of a 1992 National Health Interview Survey, researchers report in the New England Journal of Medicine that people who have the greatest need for testing but the least access to HIV testing and medical care may be the most likely to benefit from HIV-1 home testing kits. For example, black and Hispanic persons, in whom the increase of HIV infections is of great concern, are likely to use home testing kits.⁴

B. Receipt of Test Results

The majority of institutions currently offering HIV testing require the client to return to the clinic to obtain their results. Because of their lifestyles and/or financial situations, this requirement may encumber certain populations from determining their HIV status, who may be better served by this home testing alternative. For example, IV drug abusers may be unlikely to return to a public health clinic to find out test results because post-test counseling is often also required. Or, working poor may be financially unable to miss work twice (once

for pretest counseling and sample drawing, and once to receive results) and/or do not have health insurance to cover the cost of a private physician office visit.

C. Current Results Notification

According to current research, as few as one-third of individuals who tested HIV positive and were notified of their results by traditional counseling methods, such as face-to-face, were satisfied with the setting and method.⁶⁻⁸ Therefore, communication of HIV test results by telephone has been proposed as an alternative, as it has previously been shown to be a valuable listening, information-giving, and referral mechanism in other ailments.¹⁴⁻²⁰

VI. Potential Adverse Effects of the Device on Health

The Home Access HIV-1 Home Collection Kit is safe and produces minimum discomfort. Of the 1,390 who entered in the two clinical studies, only 14 (1%) reported any adverse events. Ten participants reported feeling dizzy, 2 reported anxiety, 1 reported syncope, and 1 participant reported ecchymosis (bruised finger). None of these adverse experiences were considered serious and no participants withdrew from the studies because of adverse experiences.

VII. Marketing History

The device has no history of being marketed in the U.S. or in any other country.

VIII. Summary of Studies

Six studies, one preclinical and three nonclinical laboratory plus two clinical, were conducted to establish the safety and efficacy of the Home Access HIV-1 Test System. The preclinical laboratory study established the stability of blood spot samples exposed to heat and humidity when packaged and shipped in an air impermeable return envelope. The results of the nonclinical laboratory studies evaluated the performance of (1) the Organon Teknika Vironostika® HIV-1 EIA tested with the product on "difficult" simulated blood spot samples (rare specimen types not expected to be encountered during the clinical trials); (2) the Genetic Systems HIV-1 LAV EIA tested with the product on "difficult" simulated blood spot samples (3) the Waldheim Pharmazeutika HIV-1 IFA on blood spot samples exposed to heat and humidity; and, (4) the laboratory precision and reproducibility study. One of the two clinical studies was conducted in the general population, the other in a high-risk population.

A. Preclinical and nonclinical Laboratory Studies

1. Dried Blood Spot Sample Stability Studies

EIA Reactivity of DBS Samples Exposed to Heat and Humidity in Three Shipping Envelopes

Previous data have demonstrated that DBS samples could deteriorate when stored or shipped under hot and humid conditions. This study compared the stability of fifty simulated DBS samples produced from well-characterized serum or plasma repository specimens (23 high positive, 17 low positive and 10 negative). The simulated DBS samples were exposed to heat and humidity (35 C and 95% R.H.) for changes in HIV-1 EIA (Organon Teknika Vironostika®) reactivity using three shipping envelopes.

When subjected to conditions of high heat and humidity, blood spot sample EIA signal-to-cutoff values were observed to decline over time. An air-impermeable envelope with desiccant protected blood spot samples from deterioration when compared to air-permeable envelopes currently recommended by NCCLS. The data presented in the table below demonstrates that low positive as well as high positive sample groups shipped and/or stored in a foil envelope with desiccant maintained at least 80% of their known EIA reactivity, while the negative sample group showed no significant increase in reactivity over fourteen days. In this study, the differential loss of signal between foil envelope with desiccant and standard mailing envelope was significant at 10 and 14 days ($p < 0.001$). EIA reactivity for DBS samples exposed to high heat and humidity is better preserved when shipped and/or stored in a foil envelope with desiccant when compared to air-permeable methods.

Barrier with Desiccant	Group Mean Signal-to-Cutoff Percent Change verses Baseline				
	Baseline	Day 4	Day 7	Day 10	Day 14
High Positives (n=23)	100%	111.8%	112.1%	114.3%	106.5%
Low Positives (n=17)	100%	109.1%	116.7%	116.7%	100.0%
Negatives (n=10)	100%	83.3%	100.0%	85.7%	83.3%
Control Envelope					
High Positives (n=23)	100%	114.3%	106.5%	103.3%	68.2%
Low Positives (n=17)	100%	115.4%	115.4%	109.1%	42.9%
Negatives (n=10)	100%	142.9%	125.0%	100.0%	60.0%

Use of Simulated Dried Blood Spot Samples with the Waldheim Pharmazeutika Fluorognost® HIV-1 Immunofluorescence Assay (IFA)

To evaluate the stability of dried blood spot samples using the IFA test system, thirty-eight serum or plasma repository specimens previously characterized for HIV status (8 high positive, 20 low positive, 10 negative) were mixed with outdated packed red blood cells, spotted onto filter paper, air dried, placed in barrier pouches with desiccant, then exposed to conditions of high heat and humidity (37 C, 90% R.H.) for up to 14 days - to simulate the extreme real world use and abuse.

All HIV-1 Western Blot High Positive Samples (n=8) were tested six times over 14 days and found IFA positive (48/48); HIV-1 Western Blot Low Positive Samples (n=20) were tested six times over 14 days and all but three were found positive (117/120) with the only negative results on day fourteen (2) plus one indeterminate result on day eleven. There were no false positives in the group of DBS samples which were categorized as HIV-1 negative (n=10, 60/60). These results are consistent with the results obtained with HIV-1 enzyme immunoassay testing (EIA), with consistent results through day 11 with a trend to loss of sample signal by day 14. This study demonstrated eleven days stability of simulated blood spot specimens when tested with IFA after being subjected to high heat and humidity.

2. Laboratory Precision and Reproducibility Studies

Six simulated blood spot specimens, one negative, four low positive and one high positive were spotted onto HACN cards (n = 270) and tested by Organon Teknika Vironostika® HIV-1 enzyme immunoassay (EIA). Three different teams of technicians punched, eluted and tested on three different plates according to package insert instructions and established procedures. All samples were correctly classified according to reactivity and the inter-assay precision was excellent as noted below.

<u>Sample ID</u>	<u>No. Replicates</u>	<u>Mean S/C</u>	<u>S.D.</u>	<u>% C.V.</u>
Negative	120	0.45	0.03	5.57
Low Pos. #1	30	4.11	0.48	11.67
Low Pos. #2	30	1.67	0.30	17.73
Low Pos. #3	30	1.33	0.15	11.51
Low Pos. #4	30	2.62	0.22	8.46
High Pos.	30	6.93	0.18	2.65

The precision and reproducibility of the Waldheim Pharmazeutika Fluorognost® HIV-1 Enzyme Immunofluorescence Assay (IFA) was evaluated in the simulated dried blood spot study reported above. In this study replicates of 38 specimens were blindly

spotted onto HACN cards, air-dried and stored from one to seven days in a high heat and humidity environment. On four separate days specimen cards were withdrawn from their specimen return pouches punched, eluted and blindly tested, verifying the reproducibility of this assay used with the Home Access HIV-1 Test System. The data are summarized below:

Specimen Category	No. Specimens	No. Replicates	No. (%) Confirmed IFA Positive
HIV-1 WB High Positive	10	40	40/40 (100%)
HIV-1 WB Low Positive	18	72	72/72 (100%)
HIV-1 WB Negative	10	40	0/40 (0%)

3. Qualification of Genetic Systems Corporation LAV EIA HIV-1 Enzyme Immunoassay (EIA) and Organon Teknika Vironostika® HIV-1 Enzyme Immunoassay (EIA) Using of Simulated Dried Blood Spot Samples

This study was performed to validate the performance of the Home Access HIV-1 Home Test System using the Genetic Systems Corporation LAV® EIA HIV-1 and the Organon Teknika Vironostika® HIV-1 enzyme immunoassay (EIA). To assess specificity and sensitivity, the evaluation was conducted with repository blood specimens of well-characterized EIA and Western Blot (WB) reactivity. Comparison was made between results of HIV-1 EIA testing of prepared serum samples and dried blood spots (DBS), as obtained with these repository specimens. This study was also performed to validate the functionality of the Waldheim HIV-1 IFA test for DBS confirmatory testing in conjunction with the Genetic Systems Corporation LAV HIV-1 EIA.

Testing of the Home Access HIV-1 Test System using both the Genetic Systems Corporation LAV® EIA HIV-1 and Organon Teknika Vironostika® HIV-1 enzyme immunoassay (EGAS) on simulated DBS samples exhibited acceptable specificity and sensitivity for the determination of the HIV-1 status of individuals compared to historical serum sample EIA and Western blot results and retesting of residual specimens.

B. Clinical Studies

1. A Multicenter Trial to Evaluate the Use of an HIV-1 Testing Program in the General Population

A five center study, comparing collection of blood spot specimens under conditions of home use to venous samples collected by a clinic phlebotomist, enrolled a total of 499 subjects (251 men, 240 women, and 8 unknown), ranging in age from 18 to 76 years, including 425 (85%) Caucasian participants. Sample adequacy of participant-collected blood spots compared to phlebotomist-collected blood spots was 97% (473/487). Four hundred seventy-three (473; 95%) of the participant-collected blood spot samples and 487 (98%) of the phlebotomist-collected blood spot samples were judged to be adequate for analysis.

Comparability of the HIV-1 test results, classified as negative, positive, uninterpretable (indeterminate), and not tested, was assessed in cross-tabulation for participant-collected blood spots vs. professionally collected venous samples. There was 100% agreement between participant-collected blood spot samples and professionally collected venous samples for the 471 participants who provided adequate samples for both. The correlation between the correct disposition of participants on the basis of the licensed screening (HIV-1 EIA) plus confirmatory (HIV-1 IFA) tests was also 100%, i.e., specificity was 100%. Of the 473 participant-collected blood spot samples, 471 had matching negative venous results, and 2 participant-collected blood spot samples were negative with no adequate venous samples. An additional 23 venous samples were negative with no adequate participant-collected blood spot samples, and 2 participants had neither participant-collected blood spot samples nor venous samples that were adequate.

Of the 499 participants, 48 (9.6%) had at least one difficulty with specimen collection. The most common difficulty, reported by 28 participants, was the need for more than two sticks to obtain an adequate blood specimen. However, of the 48 participants who had any difficulty, 36 (75%) were able to provide an adequate blood spot sample for testing.

Overall, results for participant-collected blood spots were available to the participant in 2.9 days (mean), with a mean of 1.4 days from specimen collection to receipt of sample at the laboratory and a mean of 1.5 days from receipt of sample at laboratory to availability of results at HAHC.

Assessment of a participant's understanding of the HIV information made available during the study was based on the number of correct responses to eight true or false questions asked during the telephone session. The mean number of correct responses to all eight statements was 7.8 (97%).

Of the 499 participants, eight (2%) reported eight adverse events - six dizziness and two anxiety. Only one of the reports of dizziness was judged to be possibly or probably related to the Home Access HIV-1 Home Collection Kit. None of these adverse events were considered serious, and no participant withdrew from the study because of an adverse event.

2. **A Multicenter Trial to Evaluate the Use of an HIV-1 Testing Program in a Population at Risk for HIV-1 Infection**

A four center study, comparing collection of blood spot specimens under conditions of home use to venous samples collected by a clinic phlebotomist, enrolled a total of 756 subjects (516 men, 231 women, and 9 unknown), ranging in age from 17 to 73 years. Of the total population of 756 subjects, 164 (22%) were found to be HIV-1 positive by serum testing. Twenty-three per cent (38/164) of those found to be HIV-1 positive were previously undiagnosed with HIV-1 infection, although sixty-five percent (65%; 488/756) of the total population reported that they had been previously tested for HIV. Sample adequacy of participant-collected blood spots compared with phlebotomist-collected blood spots was 98% (680/695). Six hundred eighty (680; 90%) of the participant-collected blood spot samples and 695 (92%) of the phlebotomist-collected blood spot samples were judged to be adequate for analysis.

Comparability of the HIV-1 test results (negative, positive, uninterpretable, and not tested) was assessed by comparing only those samples which were adequate for both for participant-collected blood spots and professionally collected venous samples. The results demonstrated 100 % agreement between participant-collected blood spot samples and phlebotomist-collected venous samples for the 676 participants who provided adequate samples for both. The correlation between the correct disposition of participants (150/150) based on the licensed screening (HIV-1 EIA) plus confirmatory (HIV-1 IFA) tests was also 100%, i.e., sensitivity was 100%.

Of the 756 participants, 73 (10%) had at least one difficulty with specimen collection. The most common difficulty, reported by 47 participants, was the need for more than two sticks to obtain an adequate blood specimen. However, of the 73 participants who had any difficulty, 56 (77%) were able to provide an adequate blood spot sample for testing.

Overall, results for participant-collected blood spots were available to the participant in 3.3 days (mean), with a mean of 1.7 days from specimen collection to receipt of sample at the laboratory and a mean of 1.7 days from receipt of sample at laboratory to availability of results at HAHC.

Assessment of a participant's understanding of the HIV information made available during the study was based on the number of correct responses to eight true or false questions asked during the telephone session. The mean number of correct responses to all eight statements was 7.6 (96%).

Of the 756 participants, six (1%) reported six adverse events - four dizziness, one ecchymosis (bruised finger), and one syncope. All of these adverse events were judged to be possibly related to the HIV-1 Home Collection Kit. However, none of these adverse events were considered serious, and no participant withdrew from the study because of an adverse event.

3. Combined Clinical Studies Summary

Based on the combined results of the two clinical studies reported here, subjects untrained in blood collection were able to obtain a specimen of adequate quantity and quality using the Home Access HIV-1 Test System 98% (1153/1182) as effectively as trained medical phlebotomists. The following table summarizes the combined disposition of all the samples during the two studies.

**Combined Disposition of Samples
in Clinical Studies (GHBA-890; GHBA-889)**

	Number (%) of Blood Spot Samples		Number (%) of Venous Samples
	Participant -Collected	Phlebotomist- Collected	
Kits Issued	1255 (100)	1255 (100)	1255 (100)
Samples Received at Laboratory	1238 (98.6)	1244 (99.1)	1243 (99.0)
Samples Evaluated by Laboratory (Adequate Samples)	1153 (91.9)	1182 (94.2)	1243 (99.0)
Samples Rejected by Laboratory	102 (8.1)	73 (5.8)	12 (1.0)
<u>Reason for Sample Rejection</u>			
Insufficient Blood on Card	82 (6.5)	62 (5.8)	-
No Blood on Card	2 (0.2)	0	-
Missing Card or Sample	17 (1.4)	11 (0.9)	12 (1.0)
Other	1 (0.1)	0	0
Number of Evaluated Sample Results Transferred to HAHC	1153 (91.9)	1182 (94.2)	1243 (99.0)

The performance of the Home Access HIV-1 Test was determined from the combined clinical trial results for 1147 subjects providing samples adequate to complete both the blood spot and venous testing algorithms. These results showed 997 of 997 (100 %) samples were negative in both test algorithms, demonstrating 100% specificity (95% confidence interval 99.6-100 %) and 150 of 150 (100 %) of samples were positive in both test algorithms demonstration 100% sensitivity (95% confidence interval 97.5-100 %). These results are summarized in the following table.

**Equivalence of HIV-1 Test Result: All Participants
Participant-Collected Blood Spots v. Venous Samples
(GHBA-890; GHBA-889)**

Participant-Collected Blood Spot Results	Venous Results				Total
	Negative	Positive	Uninterpretable	Not Tested	
Negative	997	0	0	4	1001 (79.8%)
Positive	0	150	0	2	152 (12.1%)
Uninterpretable	0	0	0	0	0
Not Tested	81	14	1	6	102 (8.1%)
Total	1078	164	1	12	1255
	85.9%	13.1%	0.1	1.0%	

Therefore, the overall accuracy of the Home Access HIV-1 Test System is estimated to be 100% ({1147 correctly identified positive + negative blood spot specimens} / {1147 correctly identified positive + negative venous specimens}).

IX. Study Conclusions

Sensitivity, Specificity, and Accuracy of the Home Access HIV-1 Test System

The sensitivity determined in the studies reported is estimated to be 100% (95% confidence interval 97.5-100 %) based on the correct identification of 150/150 positive samples compared to matched serum specimens.

1. The specificity determined in the studies reported is estimated to be 100% (95% confidence interval 99.6-100%) based on the correct identification of (997/997) negative samples compared to matched serum specimens.
2. The accuracy of the Home Access HIV-1 Test System is therefore estimated to be 100% (95% confidence interval 99.7-100%) based on correct identification of 1147/1147 clinical trial specimens.

Sample Adequacy

The ability of unskilled users to collect and ship a single blood spot of adequate quantity and quality to complete the testing algorithm compared to samples drawn by medical phlebotomists was estimated to be 98% (1153/1182). Of 1238 blood spot specimens received at the laboratory, 1153 (93 %) were judged adequate in quality and quantity to complete the testing algorithm.

Specimen Stability

Specimens spotted on Home Access Specimen Collection Cards, shipped and stored in the Home Access Specimen Return Pouch under extreme heat and humidity were shown to exhibit acceptable stability for 10 days.

Reproducibility

The standard deviations and percent coefficients of variation observed in three runs of enzyme immunoassay, demonstrated both intra- and inter-assay signal-to-cutoff values of replicate specimens, drawn from the assay dynamic range, fell well within expected values. This demonstrates the Home Access HIV-1 Test System is both accurate and reproducible. Results of replicate analyses conducted over four days on blinded specimens with the immunofluorescence assay used to confirm EIA reactive specimens was also excellent.

X. Benefit Analysis

The Home Access HIV-1 Test System will encourage the entry of infected individuals into the health care delivery system through the referral services offered to each newly diagnosed HIV-1 client. Early entry into treatment programs has been shown to be beneficial to certain populations.^{11,12} Uninfected users may benefit by increasing their knowledge about prevention of HIV infection.

With approval of the Home Access HIV-1 Home Collection Kit, public health officials will be able to dispense collection kits in areas of target populations. Access to results and counseling over the telephone will eliminate the need for clinic visits. The availability of home tests may shift the primary location of HIV testing, free up resources for other activities at public clinics, and ultimately reduce costs to the government for these services.⁴ The need to overcome the obstacles to HIV testing mandates the development of viable alternatives to more traditional testing, counseling, and treatments, which have proven less than satisfactory.^{3,5-10}

XI. Post-Marketing Studies

In order to determine the benefit of the HIV-1 test system in actual practice, HAHC will perform Phase IV monitoring studies following PMA approval and commercialization of the product according to the outline attached. The primary objectives of this study will be to (1) verify the safety and efficacy of the Home Access HIV-1 Test System under conditions of routine use so as to provide early warning should unexpected incidence of adverse events occur, and (2) assess the public health impact of the product by comparing test result utilization and acceptance of healthcare referrals by public health clients and Home Access clients. These two questions will be studied for a minimum of one year

post-approval, subject to assessment at the end of the year by FDA/HAHC, and regular reports will be made to FDA.

A secondary objective of the study will be to augment public health disease surveillance efforts by tracking the number of HIV tests performed and their results, the demographic and risk profile of the users, the number of patients seeking initial evaluation for HIV infection, and, incidence of adverse consequences. This data will be captured for a minimum of three years post-approval, subject to annual assessment by FDA/HAHC, with regular reports made to both FDA and participating local public health agencies.

Credentialed principle investigator(s) will be named from U.S. Public Health Service or academic medicine. All state public health services and selected municipal public health services will be invited to participate. Public health agencies would be encouraged to participate via the grant of Home Access Standard product based on their 1995 testing volume and their commitment to enter participants. This product would be used for local distribution, e.g., street corners in endemic areas.

A report containing the final protocol and software verification will be provided to the Agency at initiation of the study. An interim report will be made within one month of the 180 day anniversary (midpoint) of the study. A final report will be made within one month of the year anniversary of the initiation of the study.

XII. PANEL RECOMMENDATIONS

The FDA Blood Products Advisory Committee met on June 22, 1994 to discuss HIV testing through home collection kits. The agenda of the meeting was reconsideration of the potential safety and effectiveness of home collection kits. The committee then discussed the issues and decided the benefits of the sale of HIV test kits over-the-counter outweigh the potential risks.

New guidance were issued on February 23, 1995 addressing blood and non-blood based home specimen collection kits for the testing for HIV antibodies. After thorough consideration, the FDA agreed that home collection kits could be approved for over-the-counter markets.

XIII. FDA DECISION

The FDA reviewed in detail the Premarket Approval submission made by this applicant and concluded that there is reasonable assurance that the HIV-Test System is safe and effective for its intended use. The sponsors facilities were inspected on 1/9/96, 4/18/96 to 4/25/96 and 5/13/96 to 5/31/96 and were found to be in compliance with current Good Manufacturing Practices (cGMP). CBER issued an approval order for the above PMA on July __, 1996.

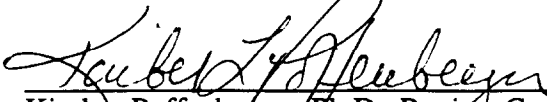
XIV. Approval Specifications

See attached labeling (Attachment A) and Conditions of Approval (Attachment B).

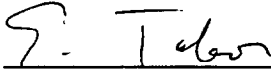
Home Access HIV-I Test System
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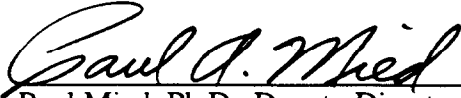
Mary Gustafson, Director
Division of Blood Applications



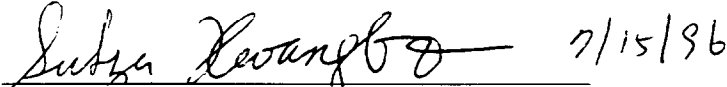
Kimber Poffenberger, Ph.D., Review Committee Chair
Division of Transfusion Transmitted Diseases



Edward Tabor, M.D., Director
Division of Transfusion Transmitted Diseases



Paul Mied, Ph.D., Deputy Director
Division of Transfusion Transmitted Diseases

 7/15/96

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