



ORAQUICK ADVANCE RAPID HIV TEST DISTRIBUTION PROGRAM

District-Wide HIV Testing Protocol

Last Updated: October 2006



**Government of the
District of Columbia
Anthony A. Williams, Mayor**



**Government of the District of Columbia
Department of Health
Administration for HIV Policy and Programs**

**64 New York Avenue, NE
Suite 5001
Washington, DC 20002**

Contents

AAHP Contacts.....	3
Summary	4
Goal and Objectives	5
Distribution Priorities.....	5
Ordering Test Kits	6
Preventing Expired Devices	6
Devices About to Expire	6
Eligibility Requirements.....	7
Quality Assurance	7
Progress Reports	8
OraQuick Rapid Test Training Schedule.....	8
Program Guidelines	9
Quarterly Reports	12
Appendices	13
Appendix 1: Inventory Log.....	14
Appendix 2: OraQuick Advance Quarterly Progress Report.....	15
Appendix 3: Confidential Client Information Form.....	17
Appendix 4: Memorandum of Understanding.....	18
Appendix 5: CDC Eligibility Requirements for CTR 2005.....	20

Administration for HIV Policy and Programs Contacts

For inquiries about the District-wide OraQuick Advance rapid HIV test distribution program, contact the following persons:

General Testing Campaign Questions:

Leo Rennie
Admin. for HIV Policy and Programs
DC Department of Health
64 New York Avenue NE, Suite 5001
Washington, DC 20002
(202) 671-4900
leo.rennie@dc.gov

Donald Hitchcock
Admin. for HIV Policy and Programs
DC Department of Health
64 New York Avenue NE, Suite 5001
Washington, DC 20002
(202) 671-4806
donald.hitchcock@dc.gov

Distribution of Rapid HIV Testing Kits:

Yasir Shah
Administration for HIV Policy and Programs
DC Department of Health
64 New York Avenue NE, Suite 5001
Washington, DC 20002
(202) 671-5074
yasir.shah@dc.gov

Training for HIV Counseling and Testing:

Cynthia Green
Administration for HIV Policy and Programs
DC Department of Health
64 New York Avenue NE, Suite 5001
Washington, DC 20002
(202) 671-5079
cynthia.green@dc.gov

Data Collection and Submission:

Tiffany LaDana West, MPH, MSPH
Administration for HIV Policy and Programs
DC Department of Health
64 New York Ave, NE 5th Floor
Washington, DC 20002
(202) 671-4921
tiffany.west@dc.gov

Summary

In collaboration with OraSure Technologies Inc., the DC Department of Health/Administration for HIV Policy and Programs (DOH/AHPP) is making available OraQuick Advance rapid HIV test kits to community-based providers and healthcare institutions to provide HIV counseling and testing services. The District of Columbia will use the OraQuick rapid test because (1) it was the first rapid point-of-care HIV test approved by the U.S. Food and Drug Administration (FDA) and (2) it is the only oral swab HIV test that the FDA waived under the Clinical Laboratory Improvement Amendment regulations (CLIA) that can effectively be used in non-clinical outreach settings.

This city-wide distribution program, in conjunction with the “Come Together DC-Get Screened for HIV” testing campaign is intended to increase the uptake of HIV testing in the District, to reduce the prevalence of unrecognized infection and to increase the proportion of infected persons who receive HIV health care and social services. Such a massive undertaking necessitates the establishment of a protocol to prevent wastage of test kits and to provide for an efficient, organized and expedient distribution process for both DOH/AHPP and program participants alike. The protocol should be regarded as a the standard for ensuring that a future supply of testing devices are available to all eligible participants when they need them.

The Department of Health/Administration for HIV Policy and Programs is working with all sectors of our community, including our schools and universities, our churches, temples, synagogues and mosques, our civic and community organizations, and our health and medical providers to ensure that the entire city comes together to eradicate HIV.

Goal & Objectives

The overarching goal of the District-wide OraQuick Advance rapid HIV test distribution program is to increase the uptake of HIV testing in clinical and non-clinical settings. Specific objectives of the program include:

1. Providing OraQuick Advance rapid test kits on a timely basis to eligible entities in accordance with specific distribution priorities and criteria in order to enhance adoption of rapid HIV testing.
2. Minimizing to the greatest extent possible the expiration and non-use of rapid HIV test devices.
3. Reporting on a quarterly basis the distribution and use of OraQuick Advance tests and the number of reactive rapid tests, by type of program participant and testing entity.
4. Obtaining relevant population based information on testing behaviors and the number of confirmed HIV positive tests to better understand the magnitude of HIV prevalence in DC.

Distribution Participants

DOH/AHPP is unable to purchase sufficient rapid HIV test devices to meet all publicly funded HIV testing needs in the District of Columbia. As a consequence, test kits will be supplied to the following entities:

1. District government agencies currently implementing HIV rapid testing
2. DOH/AHPP funded CTR providers
3. Non-DOH/AHPP-funded
4. Hospitals
5. Private medical practitioners

Among the distribution participants, preference for distributing test kits will be given to those entities that minimize wastage of devices due to their expiration and maximize identification of HIV positive individuals.

Ordering Test Kits

For new program participants, DOH/AHPP will supply in the first shipment sufficient test kits for up to a six month period. In subsequent orders to reduce waste of test kits, DOH/AHPP will only supply eligible entities sufficient test kits to meet expected needs for a three-month period. In accordance with program requirements, program participants must document on a monthly basis the utilization and number of available OraQuick Advance devices. When less than a three-month supply of devices remains, submit a re-supply order in accordance with quarterly progress reports.

Preventing Expired Devices

Unless notified by OraSure, OraQuick Advance rapid HIV test devices have a maximum shelf life of 6 months from the date of manufacture. Because of the relatively short shelf life, program participants should monitor usage closely. Clearly mark boxes with the kit expiration date and use boxes with earlier expiration dates first. Routinely identify and flag devices that are within two months of expiration. Use these devices first. DOH/AHPP will assist sites in redistributing devices that are close to expiring to sites that can use them. Do not allow devices to expire on the shelf.

Note: Expired OraQuick Advance devices cannot be used for running positive and negative controls required by the FDA.

Devices About to Expire

For test devices that are flagged to expire within two months and which may not be used before their expiration, contact Yasir Shah at the DOH/AHPP Bureau for HIV Prevention, Intervention and Services Division at yasir.shah@dc.gov or (202) 671-5074 to have the devices redistributed to another program participant.

Eligibility Requirements

To order OraQuick Advance rapid HIV tests for the first time, participants must complete and provide appropriate documentation addressing the following:

1. Clinical Laboratory Improvement Amendments (CLIA) certification or certification of waiver;
2. A rapid-test quality assurance plan;
3. Documentation that all rapid test operators are adequately trained in accordance with DOH/AHPP training and certification standards;
4. Memorandum of Understanding (Appendix 4); and
5. Meet all criteria delineated in the DOH/AHPP Eligibility Checklist for CTR Rapid Test Providers (Appendix 5).

To order a supply of OraQuick Advance rapid tests, participants must meet the five conditions above and have submitted a complete HIV testing progress report (Appendix 2) upon your initial order and every three months thereafter (quarterly). Entities that have not met all of these requirements will not be able to receive test kits through this program.

Memorandum of Understanding

Upon entry into the HIV testing distribution program, participating agencies must enter into a memorandum of understanding with DOH/AHPP and agree to the conditions outlined in this protocol (Appendix 4). By signing the memorandum of understanding, agencies will commit to meet the entire distribution participant responsibilities described in the protocol.

Quality Assurance

In accordance with FDA and CLIA regulations, all rapid HIV test programs must institute a quality assurance program which includes a system to train rapid test operators. National quality assurance guidelines are available at the following web site: http://www/cdc/gov/hiv/rapid_testing/materials/QA-Guide.htm. Each participant who receives rapid tests through this program will be required to submit their quality assurance plan as an appendix to their initial HIV testing progress report upon entry into the distribution program (Appendix 2). If the submitters' quality assurance plan is found not to be in compliance, program participants will be notified that they will need to resubmit the quality assurance plan prior to receiving additional test kits.

Progress Reports

All rapid test distribution program participants must complete and submit all testing reports on a timely basis. Upon entry into the rapid test distribution program, participants will be required to submit an estimate on the number of tests that their program will anticipate using over the next 3-6 months.

- The Inventory Log (Appendix 1) - due every three months (quarterly)
- HIV testing Quarterly Progress Report (Appendix 2) - due every 3 months (quarterly)
- Confidential Client Information Forms (Appendix 3)- due monthly

Completing these reports within the specified guidelines is essential to meet DOH/AHPP reporting needs on the distribution, use, and infection outcomes of OraQuick Advance rapid HIV test devices.

OraQuick Rapid Test Training Schedule

The Administration for HIV Policy and Programs in conjunction with OraSure Technologies will provide training on a monthly basis. Regular scheduled trainings will occur (except where noted) on the fourth Wednesday of every month at 64 New York Avenue, NE, Ste 5001 according to the following training schedule.

- Wednesday, October 18, 2006 (3rd Wednesday)
- Wednesday, November 15, 2006 (3rd Wednesday)
- Wednesday, December 20, 2006 (3rd Wednesday)
- Wednesday, January 24, 2007
- Wednesday, February 28, 2007
- Wednesday, March 28, 2007
- Wednesday, April 25, 2007
- Wednesday, May 23, 2007
- Wednesday, June 27, 2007
- Wednesday, July 25, 2007

For additional information and to register for the OraQuick Rapid Test trainings please contact Cynthia Green at cynthia.green@dc.gov or (202) 671-5079. Training schedule is subject to change.

Program Guidelines

Request Phase

Program participants will do steps 1 through 5:

1. OraQuick Advance Test Kit Quarterly Progress Report:

As required, eligible participants should submit a completed OraQuick Advance Test Kit Quarterly Progress Report upon their initial entry into the rapid HIV test distribution program (Appendix 2). All information required to confirm eligibility should be included in the initial submission. Requirements include:

- A. Clinical Laboratory Improvement Amendments (CLIA) certification or certification of waiver;
- B. A rapid-test quality assurance plan;
- C. All rapid test operators are adequately trained in accordance with DOH/AHPP training and certification standards; and
- D. Meet all criteria delineated in the DOH/AHPP Eligibility Checklist for CTR rapid test providers.

2. Estimate the number of test devices needed on a monthly basis over a 12-month period.

Complete all necessary identifying information on the inventory log (Appendix 1). Using the inventory log, estimate the total number of OraQuick Advance test devices you will need on a monthly, quarterly and annual basis for the calendar year. Fill in the row “Estimated Monthly Device Usage”. If your anticipated needs change, please update your estimates quarterly.

Example: A program participant expects to use 10,500 rapid tests in 2007. The estimated average monthly usage is 875 devices ($10,500 / 12$) and the quarterly usage is approximately 2650 devices (875×3).

3. Conduct monthly inventories of OraQuick Advance test devices.

At the end of each month using the inventory log (Appendix 1), obtain an inventory of available OraQuick Advance test devices. Calculate the monthly use index by using the following formula: Sum the number of tests on hand and divide the sum by the monthly usage. If the answer is ≤ 3 , you may need to reorder test kits. If the answer is > 3 , you should have sufficient test kits and a reorder is not necessary. DOH/AHPP will not distribute test kits if a program participant has greater than a 3-month supply of OraQuick

Advance test devices. *If you are have a special need for extra kits please add that information in the comments field.*

4. “Come Together DC-Get Screened for HIV” - HIV Testing Report

Program monitoring and evaluation is a critical aspect of the HIV testing distribution program. Monitoring and evaluation give the agency and the community a means of tracking the effectiveness and efficiency of various testing programs and efforts. The Confidential Client Information form (Appendix 3) is a self or staff administered questionnaire to be given to each client tested and can be filled out while waiting for their results. ***As with all testing information, the information on the questionnaire will be used for surveillance purposes only and is strictly confidential. The reports are to be submitted monthly and are a requirement of program participation.***

5. Submit documents to DOH/AHPP

Eligibility documents and the initial Quarterly Progress Report must be submitted prior to the receipt of the rapid tests by distribution program participants. The following documents should be faxed to Yasir Shah at (202) 671-4860 or email to yasir.shah@dc.gov.

- A. CLIA certification laboratory number
- B. Quality-assurance plan
- C. Individuals who have been trained to perform the OraQuick Advance test.
- D. Memorandum of Understanding (Appendix 4)
- E. DOH/CTR Eligibility Checklist

The inventory logs and quarterly reports (Appendices 1 and 2) should be submitted ***quarterly*** via email to Tiffany LaDana West at tiffany.west@dc.gov. In the subject line, please write: “[Organization Name]: Quarterly Progress Reports” by the 10th of the month. Confidential Client Information forms (Appendix 3) should be mailed ***monthly*** to Tiffany LaDana West at the address below.

AHPP/DOH/DC
HIV/AIDS Surveillance and Epidemiology Division
Attn: Tiffany LaDana West
64 New York Ave, NE 5th Floor
Suite: 5001
Washington, DC 20002

6. DOH/AAHP Responsibilities

A. DOH/AHPP will allocate OraQuick Advance devices to entities listed in the aforementioned section entitled “Distribution Participants”. Depending on available funding and priority level, program participants may receive fewer devices than requested or no devices at all.

B. DOH/AHPP will schedule the shipment of test kits that cover a maximum three-month period of expected use after the initial 3-6-month distribution.

C. DOH/AHPP will use the internal databases to track test kits that are obtained from the DOH/AHPP office. DOH/AHPP staff must make certain to collect the reports for each quarter prior to distribution of additional kits.

D. In order to better measure the effects of the “Come Together DC-Get Screened for HIV” campaign, all Confidential Client Information forms must be submitted to the DOH/AHPP program evaluator monthly.

E. Please note that DOH/AHPP reserves the right to conduct site visits in order to review inventory and documents related to the distribution program for purposes of verifying accurate reporting.

Delivery and Shipment Phase

OraSure Technologies will do the following:

1. After ensuring that all required documents are complete and all eligibility requirements met, DOH/AHPP will request that OraSure ship the test devices to DOH/AHPP and program participants can schedule a time collect the tests or DOH/AHPP will notify OraSure to ship the OraQuick Advance devices directly to the program participant. The shipping method will be decided on a case-by-case basis.
2. If you do not receive kits on a timely basis please contact Yasir Shah at (202) 671-5074 or yasir.shah@dc.gov.

OraQuick Advance Quarterly Progress Report

The inventory log and quarterly progress reports (Appendices 1-2) are required to record the quarterly use of OraQuick Advance test devices. Each report is for one calendar quarter. The quarterly report collects information on the program participation and outcomes such as type of testing facility, receipt and use of OraQuick Advance test devices, frequency of use, and the number of persons with confirmed reactive rapid and conventional test results. Use the comment field in the quarterly report to record adverse events associated with using rapid tests.

After completing quarterly reports, keep a copy of the file containing data for the current quarter and all previous quarters for your records, and send a copy of the file as an e-mail attachment to tiffany.west@dc.gov in accordance with the following schedule:

Quarter	Dates	Submit Report Before:
Q3-2006	July 1 – Sept. 30, 2006	October 30, 2006
Q4-2006	Oct. 1 – Dec. 31, 2006	January 31, 2007
Q1-2007	Jan. 1- Mar.31, 2007	April 30, 2007
Q2-2007	Apr. 1-Jun. 30, 2007	July 31, 2007
Q3-2007	Jul. 1 – Sept. 30, 2007	October 30, 2007

Confidential Client Information Form

Program monitoring and evaluation is a critical aspect of the HIV testing distribution program. Confidential Client Information forms give the agency and the community a means of tracking the effectiveness and efficiency of various testing programs and efforts. Each form (Appendix 3) is to a self administered or interviewer administered questionnaire to be given to each client tested and is to be filled out while they wait for their results. ***As with all testing information, the information on the questionnaire will be used for surveillance purposes only and is strictly confidential.*** Shaded fields are to be filled in by agency personnel prior to being delivered to AHPP. All program evaluation forms should be mailed ***monthly***. Please mail to:

AHPP/DOH/DC
HIV/AIDS Surveillance and Epidemiology Division
Attn: Tiffany LaDana West
64 New York Ave, NE 5th Floor
Suite: 5001
Washington, DC 20002

Should you have any questions on how to complete the form, contact Tiffany LaDana West at tiffany.west@dc.gov.

APPENDICES

GOVERNMENT OF THE DISTRICT OF COLUMBIA
Administration for HIV Policy and Programs
Inventory Log



Date _____
 Name _____
 Organization _____
 Telephone _____
 Email _____
 Organization Type (See codes below) _____

Quarter Q1 Q2 Q3 Q4
 Estimated Annual Usage _____
 Estimated Quarterly Usage _____
 Number of devices received on initial/last order _____

Inventory Log	Q1 (Example)			Q2			Q3			Q4		
	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
Estimated Monthly Device Usage:	100	150	300	125	100	700	600	800	500	300	100	100
1. No. of devices on hand ^a	100	250	450									
2. Number of tests used this Month ^b	50	100	100									
3. Monthly supply rate (#1 / #2) ^c	2.0	2.5	4.5									
4. Order? ^d	Y N	Y N	Y N	Y N	Y N	Y N	Y N	Y N	Y N	Y N	Y N	Y N

^a Sum the number of available OraQuick Advance test devices distributed through the HIV testing distribution program at the end of each month. Write answer in corresponding cell.

^b Input in the corresponding cell the monthly usage:

^c At the end of each month, divide the number of available devices by the monthly usage. Write answer in corresponding cell.

^d If the answer in the above cell is ≤ 3 , circle Y and order another 3-month supply of OraQuick Advance test kits. If answer is > 3 , circle N and do not place an order.

Organization Codes:

☐ HIV/CTS: **01** ☐ STD Clinic: **02** ☐ Drug Treatment: **03** ☐ Family Planning: **04** ☐ Prenatal/OBO Office: **05** ☐ TB Clinic: **06** ☐ Prison/Jail: **07**
☐ Community Sponsored Health Event: **08** ☐ Primary Physician: **09** ☐ Hospital ER: **110** ☐ Hospital Labor and Delivery: **111**
☐ Hospital Other : Specify _____: **112** ☐ Other, Specify _____: **113** ☐ Community Health Clinic: **114**

GOVERNMENT OF THE DISTRICT OF COLUMBIA
Administration for HIV Policy and Programs
OraQuick Advance Quarterly Progress Report



Instructions: To request OraQuick Advance tests please submit this report upon initial order and on a quarterly basis, thereafter. Please provide DOH/AHPP with the information/documentation identified below.

1. Program Manager Contact Information:

Name _____
Title _____
Organization _____
Address _____
Address _____
City _____ State _____ Zip _____
Phone _____ Fax _____
E-mail _____

I attest by my signature that all of the information provided is correct and accurate.

Signature: _____

Date: _____

2. OraQuick Advance Test Kit Order:

Please provide us with the estimated number of OraQuick Advance devices you will need to cover a three-month period.

NUMBER OF KITS REQUESTED

Have your ordered tests kits through the testing distribution program before?

No _____ Yes _____ If Yes, last order date _____ quantity _____

3. HIV Prevention Funding Sources:

Have you been funded by the following agencies to perform HIV testing and/or prevention projects? Please circle all that apply.

CDC AHPP SAMHSA HRSA DOH OTHER _____

4. CLIA Certificate of Waiver CLIA Lab Certification Number:

CLIA certificate expiration date: __/__/__

Please provide a copy of your CLIA certificate of waiver or CLIA lab certification number via fax to Yasir Shah at (202) 671-4860.

5. Quality Assurance/Quality Control Plan:

Please provide a copy of your quality assurance plan for testing sites to Yasir Shah by fax to (202)-671-4860 or e-mail the document to yasir.shah@dc.gov. In the subject line please write: “[Organization Name]: Quality Assurance Plan”. Once your quality assurance plan has been approved by DOH/AHPP, you will be notified via email and will not be required to re-submit this information quarterly. If changes to your quality assurance plan are necessary, you will be contacted via email in regards to required changes and must submit a modified plan with your next progress report.

6. Training on HIV rapid testing:

Please provide the number of persons who will administer the rapid tests, the dates these individuals were trained, and method of training (by DOH/AHPP or OraSure). If there are changes to the list quarterly, please update the information as needed. *Please note that DOH/AHPP and/or OraSure provide monthly rapid test training. If additional training is needed please contact Cynthia Green at cynthia.green@dc.gov.*

Tester Name	Date of Training	Training Provided By

Comments: _____

FOR OFFICIAL DOH USE ONLY:

RECEIVED DATE:	Initial:	DATE ORDER FILLED:	Initial	DATE ORDER SHIPPED	Initial

GOVERNMENT OF THE DISTRICT OF COLUMBIA
Administration for HIV Policy and Programs
Confidential Client Information Form



Instructions: Please fill out the following information in conjunction with the "Come Together DC, Get Tested for HIV" testing campaign. All information will be kept confidential and will be used for surveillance purposes only.

Date (Month/Year) _____ Zip _____ Residential
 Ward _____
 Street Address (optional) _____

<p>Race/Ethnicity:</p> <p><input type="radio"/> White, non-Hispanic</p> <p><input type="radio"/> Black, non-Hispanic</p> <p><input type="radio"/> Hispanic</p> <p><input type="radio"/> Asian/Pacific Islander</p> <p><input type="radio"/> American Indian, Alaskan Native</p> <p><input type="radio"/> Other, Specify _____</p> <p><input type="radio"/> Undetermined</p> <p>Sex:</p> <p><input type="radio"/> Male <input type="radio"/> Female</p> <p>Transgender <input type="radio"/> MTF <input type="radio"/> FTM</p> <p>Date of Birth (mm/dd/yyyy) _____</p>	<p>Previous Testing</p> <p>Prior to your test today, have you ever had an HIV test?</p> <p><input type="radio"/> No</p> <p><input type="radio"/> Yes</p> <p>If yes, when was your last test:</p> <p>(month/year) _____</p> <p>What was your HIV test result the last time you were tested?</p> <p><input type="radio"/> Negative</p> <p><input type="radio"/> Positive</p> <p><input type="radio"/> Unknown</p> <p><input type="radio"/> Inconclusive</p>
<p>Reason for testing: (Check all that Apply)</p> <p><input type="radio"/> Print, radio, or TV advertisement encouraging HIV testing</p> <p><input type="radio"/> Test was offered by doctor, nurse, or other care provider</p> <p><input type="radio"/> I was worried that I might have been exposed to HIV</p> <p><input type="radio"/> I get tested on a regular basis and it was time to get tested again</p> <p><input type="radio"/> I was checking to make sure I was HIV negative.</p> <p><input type="radio"/> I was required to get tested by either insurance, military, court order or by some other agency.</p> <p><input type="radio"/> I was pregnant.</p> <p><input type="radio"/> Other reason: _____</p> <p>Would you have requested an HIV test today if it were not offered to you?</p> <p><input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Not sure</p>	
<p>For Official Use Only: To be filled out by provider: Site Name</p>	
<p>Lot Number _____</p> <p>Test Result:</p> <p><input type="radio"/> Preliminary Positive</p> <p><input type="radio"/> Negative</p> <p><input type="radio"/> Inconclusive</p> <p><input type="radio"/> No Result given</p> <p>Service Referral:</p> <p><input type="radio"/> Care and Treatment</p> <p><input type="radio"/> Prevention</p> <p><input type="radio"/> No Referral</p>	<p>Type of Test:</p> <p><input type="radio"/> Anonymous: No personal Information</p> <p><input type="radio"/> Confidential: Personal Information was collected</p> <p>Site Type:</p> <p><input type="radio"/> HIV/CTS <input type="radio"/> TB Clinic</p> <p><input type="radio"/> STD Clinic <input type="radio"/> Drug Treatment</p> <p><input type="radio"/> Family Planning <input type="radio"/> Prenatal/OBO Office</p> <p><input type="radio"/> Prison/Jail <input type="radio"/> Primary Physician</p> <p><input type="radio"/> Community Sponsored Health Event</p> <p><input type="radio"/> Hospital ER <input type="radio"/> Hospital Labor and Delivery</p> <p><input type="radio"/> Hospital Other: _____</p> <p><input type="radio"/> Academic Health Center</p> <p><input type="radio"/> Other, Specify _____</p>

GOVERNMENT OF THE DISTRICT OF COLUMBIA
Administration for HIV Policy and Programs
Memorandum of Understanding



As a partnering agency representative, I, the undersigned, have read and agreed to the conditions outlined in this OraQuick Advance Rapid HIV Test Distribution Program Protocol. I understand that by signing this agreement I have committed my agency to meet all of the Distribution Participant responsibilities described in the protocol and summarized below. In signing this agreement, I understand that I have entered _____ (hereafter referred to as the Distribution Participant) into a service partnership with the Department of Health/Administration for HIV/AIDS Policy and Programs from date signed until September 30, 2007. Each entity's core responsibilities are outlined below.

Services

Distribution Participant and DOH/AHPP agree to the following stipulations:

- 1) DOH/AHPP will provide OraQuick Advance HIV rapid testing kits on a timely basis to the Distribution Participant to cover three month periods of expected use (the first shipment will be a six month supply, subsequent shipments will be for a three month supply).
- 2) After ensuring that all required documents are completed and all eligibility requirements met, DOH/AHPP will either notify OraSure to ship the OraQuick Advance devices directly to the program participant or DOH/AHPP will request that OraSure ship the test devices to DOH/AHPP and the Distribution Participant can schedule a time to come and collect the tests. The shipping method will be decided on a case-by-case basis.
- 3) DOH/AHPP will be responsible for establishing and maintaining internal tracking mechanisms to track tests obtained by the Distribution Participant from the DOH/AHPP office.
- 4) DOH/AHPP will ensure that the Distribution Participant has been provided the contact name and information of the appropriate DOH/AHPP provided staff for the Distribution Participant to submit the all ordering, tracking, monitoring and program evaluation tools.
- 5) DOH/AHPP will conduct site visits to ensure quality control and to review inventory and documents related to the distribution program for the purpose of verifying accurate reporting.
- 6) Distribution Participant will be responsible for e-mailing a DOH/AHPP identified contact with the date of shipment for the OraQuick Advance devices and the number of kits received.
- 7) Distribution Participant will closely monitor characteristic information on the population utilization of OraQuick Advance devices on a monthly basis (Appendix 3) according to the instructions provided within the protocol and mail the attachments to the DOH/AHPP identified contact person. The Distribution partner shall maintain a record of when the information was sent to DOH/AHPP.
- 8) Distribution Participant will submit a re-supply order in accordance with the instructions on the Request Form (Appendix 2).

Appendix 4

- 9) Distribution Participant will not allow test devices to expire on a shelf and will be responsible for notifying DOH/AHPP at 671-5074 of any devices that are within two months of expiration for possible redistribution to a higher volume partnering site.
- 10) Distribution Participant will, in accordance to the quarterly schedule, use the attached Appendix 1 to record the quarterly use of OraQuick Advance test devices according to the instructions provided within the protocol and e-mail the attachment to the DOH/AHPP identified contact person. The Distribution Partner will maintain a copy of all reports in their records.
- 11) Distribution Participant will provide DOH/AHPP with an updated list of key contact personnel responsible for managing the OraQuick Advance Rapid HIV Testing Distribution program and individuals responsible for maintaining and submitting the required documentation and reporting for distribution participants.
- 12) Distribution Participant will ensure that all staff responsible for administering OraQuick Advance HIV rapid tests will be trained in accordance to DOH/AHPP guidelines prior to utilizing the OraQuick Advance kits. Distribution Participants recognize that it may be required to provide DOH/AHPP with proof of testing staff training.

Length of this Agreement

This agreement will be in place from date signed until September 30, 2007 as the mutually understood arrangement between DOH/AHPP and Distribution Participant for the agreed to service delivery stated herein during the specified period.

Either DOH/AHPP or the Distribution Participant may end this service agreement at will. However, both DOH/AHPP and Distribution Participant mutually agree as a courtesy to provide a fourteen-day (14) notice to the other party should either desire to end or renegotiate this arrangement.

DOH/AHPP and Distribution Participant agree to meet on a consistent and mutually determined schedule to review services, testing coordination to meet the goals of the DOH/AHPP testing campaign and to best serve the Distribution Participant's clients.

Signed

Date: _____

Name

Title

Agency/Organization/Entity

GOVERNMENT OF THE DISTRICT OF COLUMBIA
Administration for HIV Policy and Programs
CDC Eligibility Requirements for Counseling, Testing, and Referral (CTR) 2006



The following is a checklist of the areas of counseling, testing, and referral activities that you need to discuss with your local health department representatives at the Administration for HIV Policy and Programs—**Cynthia Green 202 671-4900**

- **Policies and Procedures for the Counseling, Testing, and Referral Program:** Written guidelines and policies for the provision of service at your agency available to all staff and part of new employee (CTR staff) orientation.
- **Anonymous versus confidential testing:** Tell what will guide your testing practices.
- **Informed Consent:** How you will ensure that your clients are fully informed before testing.
- **Training of counselors:** List the number of staff who have been trained and those who need training. For those who need training, provide what entity will do the training, and when the training be held. Ensure that you meet state and local regulations. Administration for HIV Policy and Programs will provide guidelines for HIV Prevention Counselor Training; **202 671-5079**
- **Confidentiality:** Provide training and forms to each staff member to sign to ensure confidentiality is respected.
- **Surveillance reporting:** Follow the guidelines set by the District of Columbia Department of Health (DOH) Administration for HIV Policy and Programs www.hivcounts.net for reporting HIV and AIDS.
- **Laboratory processing:** Tell how you have set up agreements to transport testing specimens to a lab for processing, what type of testing you are offering [e.g., rapid test, serum, oral fluid, etc.], and how lab processing will be funded. **Dr. Maurice Knuckles, Director DC Public Health Laboratory 202 727-8956.**
- **Type of testing:** Determine what types of testing you are using—OraSure, OraQuick Advance, etc.) Brandon Dubroc, OraSure Technologies at **484-553-6579** or bdubroc@orasure.com
- **Follow-up for results, especially of those persons who are infected with HIV:** Create a plan to follow-up with those persons who are HIV infected and do not return for their results.
- **Early intervention services for HIV infected persons:** Create a plan to make sure persons who are infected and know their status are aware of and linked to primary medical, case management, substance abuse treatment, prevention case management and other appropriate services.
- **Data collection and reporting:** Make sure your collection and reporting methods are congruent with the local department of health.
- **Quality Assurance Protocols:** QA protocols should be written and routinely implemented for the following: Service accessibility; compliance with written protocols, guidelines and performance standards; data management; specimen collection; community resources; staff safety in non traditional settings; services and materials; evaluation of staff performance and proficiency that should comprise DOP (Direct observation of Performance); and supervision of staff. **202 671-5079**

- **Linkages with partner notification (PCRS):** Administration for HIV Policy and Programs will assist with the notification of the sex and/or needle-sharing partner(s) of a person infected with HIV. Each agency must refer these individuals (with supporting documentation) to AHPP for Partner Counseling and Referral Services (PCRS). **The wording should indicate how the organization plans to offer PCRS and link with the AHPP PCRS Coordinator at 202 671-5080.**
- **Synchronized with local laws:** Make sure you are in line with any laws in your area (actual location of testing site) concerning CTR such as the DCMR Title 22 (DC Municipal Regulations-Public Health and Medicine governing the Protection of Minors, Informed Consent, HIV and AIDS Reporting and Confidentiality and Security. **202 671-5079**
- **Populations to be targeted:** Know which priority population(s) you will provide services to and the available resources.
- **Standing orders with a physician.** You must provide a letter of intent from a physician with your application and a memorandum of agreement if selected for funding.
- **Referral Network:** Identify potential partners (collaborations) to increase the number of individuals who receive comprehensive services. Develop a formal agreement such as a memorandum of understanding (MOU) with each agency. **Develop systems to track referral activities.** (Refer to: *Fundamentals of Prevention Counseling and/or MMWR—Guidelines for HIV Counseling, Testing, and Referral and Revised Recommendations for HIV Screening of Pregnant Women , 2001l*)

Establish a formal agreement with a laboratory and provide a plan for ensuring training, oversight, quality assurance, and compliance with CLIA requirements and relevant state and local regulations applicable to waived testing, if your agency will be using a waived rapid HIV antibody test.

Obtain a CLIA Certificate of Waiver or approval to operate under that laboratory's CLIA certificate:

**Department of Health
Health Regulation Administration
Health Care Facilities Division
Laboratory Certification & Licensure Section
825 North Capitol Street, N.E.
Room #2241
Washington, D.C. 20002 (202) 442-4706**

Submit a letter of support from the laboratory.

- ✕ Sample collection kits (OraQuick)
- ✕ Sample collection kits (OraSure)
- ✕ Equipment/support supplies to draw blood for confirmatory tests
- ✕ Support supplies for OraQuick/OraSure/Serum Blood draw, etc.
- ✕ Lab forms
- ✕ HIV CTS Report (bubble sheet) forms (Keith Floyd 202 671-4994)
- ✕ Sample Processing for OraSure
- ✕ Sample processing for confirmatory tests—must collect blood samples to confirm rapid testing preliminary positives. (*Letter dated July 29, 2005*)
- ✕ Pickup of samples (OraSure and confirmatory)
- ✕ Delivery of results to CBO's (OraSure and confirmatory)