S. S. R. B.
DATE 11/18/09
APPROVED 3-0
CONDITIONALLY APPROVED
RETURN TO DEPT.
DISAPPROVED

CITY OF CHICAGO
DEPARTMENT OF PROCUREMENT SERVICES
ROOM 403, CITY HALL, 121 N. LA SALLE ST.

JNC

JUSTIFICATION FOR NON-COMPETITIVE PROCUREMENT

COMPLETE THIS SECTION IF NEW CONTRACT

For contract(s) in this request, answer applicable questions in each of the 4 major subject areas below in accordance with the Instructions for Preparation of Non-Competitive Procurement Form on the reverse side.

Request that negotiations be conducted only with OraSure Technologies Incorporated for the product and/or services described herein.
(Name of Person or Firm)

This is a request for ___ (One-Time Contractor Requisition # 23802, copy attached) or _XXX_ Term Agreement or Delegate Agency _____ (Check one). If Delegate Agency, this request is for "blanket approval" of all contracts within the _____ (Attach List)
Pre-Assigned Specification No. (Program Name) _____
Pre-Assigned Contract No. _____

COMPLETE THIS SECTION IF AMENDMENT OR MODIFICATION TO CONTRACT

Describe in detail the change in terms of dollars, time period, scope of services, etc., its relationship to the original contract and the specific reasons for the change. Indicate both the original and the adjusted contract amount and/or expiration date with this change, as applicable. Attach copy of all supporting documents. Request approval for a contract amendment or modification to the following:

Contract #: _____ Company or Agency Name: _____

Specification #: _____ Contract or Program Description: _____
Mod. #: _____(Attach List, if multiple)

Paul LaKosky	747-9655		Health	09/08/05
Originator Name	Telephone	Signature	Department	Date

Indicate SEE ATTACHED in each box below if additional space needed:

( ) **PROCUREMENT HISTORY**
The City of Chicago has had a term agreement with OraSure Technologies since 2002. This supply requirement cannot be competitively bid as OraSure Technologies, Inc. ("OraSure") is the only licensed manufacturer and sole distributor of the OraQuick® Advance Rapid HIV – 1/2 Antibody Test, OraSure oral fluid HIV-1 anti-body collector device, and the OraQuick® Advance Rapid HIV – 1/2 Controls.

( ) **ESTIMATED COST**
$300,000 per year for 3-years Total Estimated Cost $900,000

( ) **SCHEDULE REQUIREMENTS**

See attached price quotes

( ) **EXCLUSIVE OR UNIQUE CAPABILITY**
OraSure Technologies, Inc. ("OraSure") is the only licensed manufacturer and sole distributor of the OraQuick® Advance Rapid HIV – 1/2 Antibody Test, OraSure oral fluid HIV-1 anti-body collector device, and the OraQuick® Advance Rapid HIV – 1/2 Controls.

( ) **OTHER**

APPROVED BY:

	10/31/05		11/19/09
DEPARTMENT HEAD OR DESIGNEE	DATE	BOARD CHAIRPERSON	DATE

Jamie L. Rhee
Chief Procurement Officer

11/19/09
Date

CPAC PROJECT CHECKLIST

For CPAC Team Use Only
Date Received
Date Returned
Date Accepted

IMPORTANT: PLEASE READ AND FOLLOW THE INSTRUCTIONS FOR COMPLETING THE PROJECT CHECKLIST AND CONTACT THE APPROPRIATE TEAM LEADER IF YOU HAVE ANY FURTHER QUESTIONS. ALL INFORMATION SHOULD BE COMPLETED, INCLUDING THE SUPPLEMENTAL CHECKLIST REQUIRED BY THE SPECIFIC CPAC TEAM. ATTACH ALL REQUIRED MATERIALS AND SUBMIT FOR HANDLING TO THE DEPARTMENT OF PROCUREMENT SERVICES, ROOM 403, CITY HALL, 121 N. LASALLE STREET, CHICAGO, ILLINOIS

PROJECT

Date: 10/6/05

ID No. (Spec, RX, Project). :40826

Department: #41 Health

Bureau:STD/HIV/AIDS

Contract No.(if known 23802

Project Title/Description New sole source term agreement to purchase OraSure testing kits for the STD/HIV Prevention program.

Contact Person: Maribel Valdez
Tel:747-8828 **Fax:**747-1031 **E-mail:**
Project Manager: Paul Lakosky
Tel:7-9655 **Fax:**7-9663 **E-mail:**
Estimated Value $900,000

SCOPE STATEMENT

_X__ Attached is a detailed scope of services and/or specification

IMPORTANT: THIS IS A CRITICAL PORTION OF YOUR SUBMITTAL. IN ORDER FOR A TEAM TO ACCEPT YOUR SUBMITTAL YOU MUST COMPLETE ALL TEAM SPECIFIC SCOPE REQUIREMENTS AS SET FORTH IN THE SUPPLEMENTAL CHECKLIST FOR THAT TEAM.

The following is a general description of what would be included in a Scope of Services or Specification:
A clear description of all anticipated services and products, including: time frame for completion, special qualifications of prospective vendors, special requirements or needs of the project, locations, anticipated participating user departments, citation of any applicable City ordinance or state/federal regulation or statute.

TYPE OF PROCUREMENT REQUESTED (check all that apply)

__Competitive Bid __RFQ/RFP/RFS/RFI X Sole Source X Term Agreement __One Shot
___ Mod/Amendment __Time Extension __Additional Funding __Small Order ___ S/O Emergency

FORMS
___F-25* (add line items) ___F-10 *(special approval) __SSRB**(Sole Source approval)
___F-26* (new term agreement) ___RX (one-shot requisition) ___ OBM Authorization
___F-27* (time extension) _X__ APRF (all purpose request form)
___F-29* (change vendor limit)

** Sole source requests must include vendor quotes/proposal and MBE/WBE compliance requirements

FUNDING

City:	_X_Corporate	___Bond	___Enterprise	_____Grant*	___ Other_____
State:	___IDOT/Transit	___IDOT/Highway		___Grant*	___Other_____
Federal:	___ FHWA	___FTA	___FAA	___Grant*	___Other_____

Funding Strips 05-100-3350-41-9129-0342

*Attach copy of applicable grant agreement terms and conditions language:

TIME FRAME

Date Needed: 1/1/07

Requested Contract Term (y/m/d): 1/1/07-12/31/10

PRE BID/SUBMITTAL REQUIREMENTS

Requesting Pre Bid/Submittal Conference? ___Yes _XNo Requesting Pre Bid/Submittal be Mandatory? ___Yes _X No
Requesting Site Visit? ___ Yes _X No Requesting Site Visit be Mandatory? ___Yes _X_No

CITY OF CHICAGO
PURCHASE REQUISITION

Copy (Department)

DELIVER TO:	REQUISITION: 23802
041-3355 DEPAUL 2FL 333 S. STATE ST. 2ND FLOOR Chicago, IL 60604	PAGE: 1 DEPARTMENT: 41 - DEPARTMENT OF HEALTH PREPARER: Maribel E Valdez NEEDED: APPROVED: 10/4/2005

REQUISITION DESCRIPTION

NEW CONTRACT FOR THE HIV/AIDS ORASURE TESTING KITS
SPECIFICATION NUMBER: 40826

COMMODITY INFORMATION

LINE	ITEM	QUANTITY	UOM	UNIT COST	TOTAL COST
1	1935244110	10,000.00	Case	0.00	0.00

HUMAN IMMUNODEFICIENCY VIRUS - RAPID HIV-1, ORAQUICK 1001-0051, 100 CT

SUGGESTED VENDOR: ORASURE TECHNOLOGIES INC **REQUESTED BY:** Maribel E Valdez

DIST	BFY	FUND	COST CTR	APPR	ACCNT	ACTV	PROJECT	RPT CAT	GENRL	FUTR	Dist. Amt.
1	005	0100	0413350	9121	220342	0000	00000000	000000	00000	0000	0.00

LINE TOTAL: **0.00**

REQUISITION TOTAL: **0.00**

Where a commodity is for a particular or unique use other than standard quality, grades, color, size or other characteristics, give details of how it will be and for what purpose.
Requisitions prepared incorrectly will be returned to the using department

CITY OF CHICAGO
PURCHASE REQUISITION

Copy (Department)

DELIVER TO:	REQUISITION: 23802
041-3350 DEPAUL 2FL 333 S. STATE ST. 2ND FLOOR Chicago, IL 60604	PAGE: 1 DEPARTMENT: 41 - DEPARTMENT OF HEALTH PREPARER: Maribel E Valdez NEEDED: APPROVED: 10/4/2005

REQUISITION DESCRIPTION

NEW CONTRACT FOR THE HIV/AIDS ORASURE TESTING KITS
SPECIFICATION NUMBER: 40826

COMMODITY INFORMATION

LINE	ITEM	QUANTITY	UOM	UNIT COST	TOTAL COST
2	1935244100	16,000.00	Case	0.00	0.00

HUMAN IMMUNODEFICIENCY VIRUS - RAPID HIV-1, ORAQUICK 1001-0052, 25 CT

SUGGESTED VENDOR: ORASURE TECHNOLOGIES INC **REQUESTED BY:** Maribel E Valdez

DIST	BFY	FUND	COST CTR	APPR	ACCNT	ACTV	PROJECT	RPT CAT	GENRL	FUTR	Dist. Amt.
1	005	0100	0413350	9129	220342	0000	00000000	000000	00000	0000	0.00

LINE TOTAL: 0.00

LINE	ITEM	QUANTITY	UOM	UNIT COST	TOTAL COST
3	1935244125	800.00	Set	0.00	0.00

HUMAN IMMUNODEFICIENCY VIRUS - RAPID HIV CONTROL, ORAQUICK 1001-0049

SUGGESTED VENDOR: **REQUESTED BY:** Maribel E Valdez

DIST	BFY	FUND	COST CTR	APPR	ACCNT	ACTV	PROJECT	RPT CAT	GENRL	FUTR	Dist. Amt.
1	005	0100	0413350	9129	220342	0000	00000000	000000	00000	0000	0.00

LINE TOTAL: 0.00

REQUISITION TOTAL: 0.00

Where a commodity is for a particular or unique use other than standard quality, grades, color, size or other characteristics, give details of how it will be and for what purpose
Requisitions prepared incorrectly will be returned to the using department

Sole Source Justification: OraSure Technologies Incorporated

In June 2003 the Chicago Department of Public Health, Division of STD/HIV/AIDS Public Policy and Programs received an award from the Centers for Disease Control and Prevention (CDC) in Atlanta, GA under the Post-Market Surveillance for OraQuick™ Rapid HIV-1 Testing Initiative. The purpose of this initiative was to conduct multi-site pilot studies to assess the feasibility and acceptability of OraSure Technologies 1st generation OraQuick rapid HIV-1 testing – a blood/whole serum-based test and at the time a new testing technology- in non-clinical settings (e.g., jails, public parks, universities, community-based organizations, etc.). CDPH partnered with 5 community-based organizations to integrate OraQuick testing into their organizations as well as introducing OraQuick into all CDPH clinics and the Sheriff's Female Furlough Program.

During Chicago's pilot study approximately 950 individuals were tested using the device. Of those tested approximately 1.9% (18) were found to be HIV positive. This represents a 1% increase is the HIV seropositivity rates over individuals tested using conventional HIV-1 testing methods. Many of the individuals tested stated that they would not have tested for HIV if the OraQuick rapid HIV-1 test had not been available as a testing option. This project was renewed in January 2004 - and extended through FY 2006- due to its continued success. Lastly, during 2005 CDPH was awarded a 5-year grant from the Substance Abuse and Mental Health Services Administration (SAMHSA) program announcement CFDA No. 93.243): Substance Abuse, HIV, and Hepatitis Prevention for Minority Populations in Communities of Color. Rapid HIV-1/2 Testing is an integral component of this program which will run through 2010.

In September 2003 the Chicago Department of Public Health, Division of STD/HIV/AIDS Public Policy and Programs received an additional award for Rapid Testing under CDC program announcement 2003-N-00894: Project 3 - Using HIV Rapid Testing to Improve Outcomes of Partner Counseling and Referral Services. This award was initially to cover the period 09-14-03 through 09-14-05, but was extended through 06-14-2006.

In November 2004 OraSure Technologies was granted FDA approval of their 2nd generation rapid HIV-1/2 test marketed under the name OraQuick Advance.™ This device is capable of detecting HIV – 1 or 2 antibodies in oral mucosal transudate (i.e., cells found in the mouth). Using this technology CDPH has conducted or facilitated the testing of 700 high-risk individuals each month in non-traditional/non-clinical settings.

OraSure Technologies, Inc. ("OraSure") continues to be the only licensed manufacturer and sole distributor of the OraQuick Advance Rapid HIV – 1/2 Antibody Test, OraSure oral fluid HIV-1 antibody collector device, and the OraQuick® Advance Rapid HIV – 1/2 Controls.

Specification:

OraSure HIV – 1 Oral Fluid Testing Device

The OraSure® HIV-1 Oral Specimen Collection Device is an oral fluid collection device that detects the presence of HIV – 1 in human oral fluid. A collection pad is placed between the lower cheek and gum for 2 to 5 minutes. OraSure® is designed to draw out HIV-1 antibodies, not the virus, from the tissues of the cheek and gum. OraSure® HIV-1 does not collect saliva but rather a sample called oral mucosal transudate (OMT).

OraSure® HIV-1 offers healthcare professionals an HIV-1 testing option without the risk of needle stick accidents and gives patients accurate results without having to give blood

OraQuick® Advance™ Rapid HIV – 1/2 Testing Kits

OraQuick® **Advance™** is an FDA approved rapid point-of-care fingerstick and venipuncture whole blood test used to aid in the diagnosis of HIV-1 infection. This Clinical Laboratory Improvements Amendments of 1988 (CLIA) waived test, which detects the presence of antibodies to HIV-1, requires only a drop of blood and can produce results in 20 minutes.

Based on the results from a large controlled clinical trial, the overall sensitivity and specificity of the OraQuick® Advance™ Rapid HIV-1 Antibody test was shown to be 99.6% and 100.0% respectively, using fingerstick and venipuncture whole blood specimens.

OraQuick® Advance™ HIV-1/2 offers healthcare professionals an HIV-1/2 testing option without the risk of needle stick accidents and gives patients accurate results without having to give blood

OraQuick® Advance™ Rapid HIV – 1/2 Controls

OraQuick® Advance™ Kit controls are human plasma-based reagents. The Kit Controls are specially formulated and manufactured to ensure performance of the Test, and are used to verify the ability of the counselor to properly perform and interpret the results. The HIV – 1 and HIV – 2 Positive Controls will produce a reactive test result and have been manufactured to produce a very faint result. The Negative Control will produce a non-reactive test result.

These supplies will be shipped to the following CDPH clinics in care of the following individuals.

CDPH Lakeview Specialty Clinic
ATTN: Rick Ortiz, Rapid Testing Coordinator
2861 N. Clark Street
Chicago, IL 60657 Phone: 312.744.5507

CDPH 31st Specialty Clinic
ATTN: Yvette Winston, Director of Administrative Services I
530 E. 31st St.
Chicago, IL 60616 Phone: 312.747.5409

Estimated Cost:

OraSure HIV – 1 Oral Fluid Testing Device

24,340 – 16, 949 OraSure HIV – 1 Oral Fluid Testing Devices @ $4.10 - $5.90ea = **$100,000**

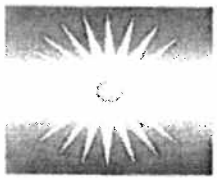
OraQuick Advance Rapid HIV – 1/2 Testing Kits

10,000 OraQuick Advance Rapid HIV – 1/2 Testing Kits @ $18.00ea = **$180,000**

OraQuick Advance Rapid HIV – 1/2 Controls

800 OraQuick Advance Rapid HIV – 1/2 Controls @ $25.00ea = **20,000**

Total Estimated Cost: **$300,000**



OraSure Technologies, Inc.

diagnostic solutions for the new millennium

September 8, 2005

Mr. Paul Lakosky
Chicago Dept. of Public Health
31st Street, Specialty Clinic
530 E. 31st Street
Chicago, IL 60616

SUBJECT: Sole Source Letter for OraQuick ADVANCE

Dear Mr. Lakosky:

OraSure Technologies, Inc. ("OraSure") is the only licensed manufacturer of the OraQuick® ADVANCE Rapid HIV-1/2 Antibody Test (the "OraQuick® Test"), PMA# BP010047, product numbers 1001-0079,1001-0078 and OraQuick® ADVANCE Rapid HIV-1 / 2 Control, P/N 1001-0077. OraSure is also the sole source for obtaining this OraQuick® Test and controls.

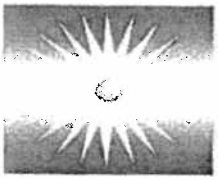
Thank you for your continued support of OraSure Technologies. If you need any further information, please contact me at 916-782-3119 or e-mail: preis@orasure.com.

Sincerely,

Patricia Reis

Patricia Reis
Contracts Administrator

220 East First Street • Bethlehem, Pennsylvania 18015-1360
Phone 610-882-1820 • Fax 610-882-1825
www.orasure.com



OraSure Technologies, Inc.

diagnostic solutions for the new millennium

September 7, 2005

Mr. Paul Lakosky
Chicago Dept. of Public Health
31st Street, Specialty Clinic
530 E. 31st Street
Chicago, IL 60616

SUBJECT: Quote for OraQuick® ADVANCE Rapid HIV-1 / 2 Kits and Controls

Dear Mr. Lakosky:

OraSure Technologies, Inc. (OTI) is pleased to provide the below listed price quote for OraQuick® ADVANCE Rapid HIV-1 / 2 kits and controls per your request for FY

Item #	Description	Case Price	Qty
1001-0079	**OraQuick® ADVANCE** Rapid HIV-1 / 2 ,25 ct	$450.00/case	As Needed
1001-0078	**OraQuick® ADVANCE** Rapid HIV-1 / 2 , 100 ct	$1800.00/case	As Needed
1001-0077	**OraQuick®** ADVANCE Rapid HIV 1 / 2 Controls	$25.00 set	As Needed

Freight is not included in the above pricing and will be billed separately. FOB point is Bethlehem, PA. Payment terms are Net 30 days from invoice date. Delivery will be 14 - 21 days ARO. OraSure's Federal ID# is 36-4370966. 60 days City terms

→ must approved the address for the point to distribute

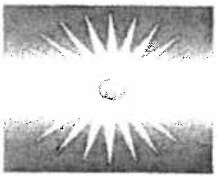
OraSure Technologies, Inc. ("OraSure") is the only licensed manufacturer of the OraQuick® ADVANCE Rapid HIV-1/2 Antibody Test (the "OraQuick® Test"), PMA# BP010047, product numbers 1001-0079,1001-0078 and OraQuick® ADVANCE Rapid HIV-1 / 2 Control, P/N 1001-0077. OraSure is also the sole source for obtaining this OraQuick® Test and controls.

Payment Address:
OraSure Technologies, Inc.
Dept. 269701
PO Box 67000
Detroit, Michigan 48267-2697

Customer Service
To place orders please call 800-869-3538 or 610-882-1820 or Fax Orders to 610-882-3572. Emails may be sent to customerservice@orasure.com. Office Hours are 8 a.m. to 6 p.m. (Eastern Time).

Thank you for your continued support of OraSure Technologies. If you need further information, please contact me at 916-782-3119 or e-mail: preis@orasure.com.

Regards,
Patricia Reis
Patricia Reis
Contract Manager



OraSure Technologies, Inc.

diagnostic solutions for the new millennium

September 7, 2005

Mr. Paul Lakosky
Chicago Dept. of Public Health
31st Street, Specialty Clinic
530 E. 31st Street
Chicago, IL 60616

SUBJECT: Quote for OraSure® HIV-1 Oral Fluid Devices, P/N 503-0050

Dear Mr. Lakosky:

OraSure Technologies, Inc. (OTI) is pleased to provide the below listed price quote for OraSure® HIV-1 Oral Fluid devices per your request.

OraSureTechnologies, Inc. is the manufacturer and sole provider of the FDA approved OraSure, oral fluid HIV-1 antibody collector device; PMA BP910001, P/N 503-0050 product as listed below. Furthermore, these collectors cannot be obtained through any distribution network in the United States and must be purchased directly from OraSure Technologies, Inc.

Item #	Description	Unit Price	Qty
503-0050	**OraSure®** HIV-1 Oral Fluid Devices, 50 ct	$295.00	Less than 20 cases per order
503-0050	**OraSure®** HIV-1 Oral Fluid Devices, 50 ct	$205.00	20+ cases per order

FOB point is Bethlehem, PA. Freight charges will be prepaid and added to your invoice. Payment terms are Net 30 days from invoice date. Delivery will be 14 - 21 days ARO. OraSure's Federal ID# is 36-4370966.

Payment Address:
OraSure Technologies, Inc.
Dept. 269701
PO Box 67000
Detroit, Michigan 48267-2697

Customer Service
To place orders please call 800-869-3538 or 610-882-1820 or Fax Orders to 610-882-3572. Emails may be sent to customerservice@orasure.com. Office Hours are 8 a.m. to 6 p.m. (Eastern Time).

Should you require additional information, please contact me at 916-782-3119.

Regards,
Patricia Reis
Patricia Reis
Contract Manager

PAGE 1 OF 1

CITY OF CHICAGO ALL PURPOSE REQUISITION FORM

DEPT USE 1	DEPT USE 2

DATE	BUREAU/DIVISION	SHIP CODE	SHIP TO: ATTN.:	DATE NEEDED	PG/RX NUMBER	PV NUMBER
					E2	

LINE TERM	LINE FUND	COMMODITY CODE	SYS CODE	DESCRIBE AND JUSTIFY GOODS OR SERVICES, OR ENTER CATALOG INFORMATION — ITEM DESCRIPTION	CATALOG NAME/#	CATALOG DATE	CATALOG PAGE	CATALOG ITEM/PART #	UNIT PRICE	UNIT OF MEASURE	QUANTITY ORDER	QUANTITY RCV'D	TOTAL PRICE
											16,000		
											10,000		

COMMENTS:

CHECK OR COMPLETE ALL THAT APPLY	
PARTICIPATING TA #	
NEW TA OR CONTRACT X	SOLE SOURCE
PURCHASE ORDER	CONTRACT AMENDMENT
DIRECT VOUCHER	EMERGENCY REQUEST
7-DAY BID	REJECTED

FY	LINE	FUND	DEPT	ORGN	APPR	ACTV	OBJT	PROJECT	RPTG	DOLLAR AMT.
06	1		11		9124					

PAGE TOTAL →

GRAND TOTAL (ALL PAGES) → $300,000

FOR FINANCE OFFICE USE ONLY	
CONTRACTS REVIEW DATE	FINANCE DIRECTOR DATE
EPS PASS 1 DATE	EPS PASS 2 DATE

VENDOR INFORMATION

COMPANY NAME
ADDRESS
VENDOR CODE
REP/PHONE

INVOICE NUMBER(S)

BUREAU/DIVISION INFORMATION

SECTION MANAGER/ APRF PREPARED BY
ADDRESS
DATE PHONE
DEPUTY AUTHORIZATION
DATE PHONE

WHITE COPY – ORIGINAL YELLOW COPY – BUREAU/DIVISION PINK COPY – FINANCE DIVISION GOLD COPY – FILE

GRC-160847-34-2

City of Chicago
Richard M. Daley, Mayor

Department of Public Health

Terry Mason, M.D., F.A.C.S.
Commissioner

333 South State Street
Chicago, Illinois 60604
(312) 747-9884
(312) 747-9888 (24 hours)

http://www.cityofchicago.org/health

February 10, 2006

Barbara A. Lumpkin
Chief Procurement Officer
Department of Procurement Services
121 North LaSalle Street – Room 403
Chicago, Illinois 60602

Subject: OraSure Technologies, Inc.
MBE/WBE Waiver Request Concurrence

The Chicago Department of Public Health (CDPH) has reviewed the MBE/WBE waver request made by OraSure Technologies, Inc. in the January 12, 2006 correspondence addressed to your office. CDPH concurs with the contractor's request based on its back up documentation submitted to request this waver.

The FDA regulations and the complicated process to evaluate and qualify vendors and contractors to produce the testing kits leaves no room for compliance with direct participation. Therefore, we concur with OraSure Technologies Inc's request for a full waver of the MBE/WBE requirement.

Your timely consideration of this request will be greatly appreciated.

If you have any questions, or need additional information, please call Peg White at 7-7696 or Maribel Valdez at 7-8828.

Sincerely,

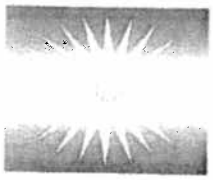
Terry Mason

Terry Mason, M.D., F.A.C.S.
Commissioner

Cc: File
Paul LaKosky
Doris Moore

NEIGHBORHOODS ALIVE!
BUILDING CHICAGO TOGETHER

CHICAGO WORKS TOGETHER



OraSure Technologies, Inc.

diagnostic solutions for the new millennium

January 12, 2006

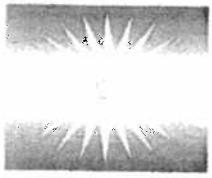
Ms. Barbara Lumpkin
Chief Procurement Officer
Department of Procurement Services
121 N. LaSalle Street, Rm. 403
Chicago, IL 60602

SUBJECT: *WAIVER REQUEST*: MBE/WBE PARTICIPATION COMMITMENTS, OraQuick® ADVANCE™ Products

Dear Ms. Lumpkin:

REASON FOR WAIVER REQUEST:

OraSure Technologies, Inc. is the sole source provider of OraQuick® ADVANCE™ products to Department of Health's. Most of our products are regulated by the FDA, certain state and local agencies, and comparable regulatory bodies in other countries. This regulated environment governs almost all aspects of development, production, and marketing, including product testing, authorizations to market, labeling, promotion, manufacturing and recordkeeping. Since OraQuick® Advance™ products are considered to be medical devices, OraSure must follow the FDA regulations which require approval by the FDA for changes to our Approved Vendors list. This is both a detailed and time-consuming process. OraQuick® ADVANCE™ kits are manufactured in our Bethlehem, Pennsylvania facility. We can purchase the HIV antigen and the nitrocellulose required for the OraQuick® test only from a limited number of sources. The antigen is currently purchased from a single contract supplier under a long-term agreement with an initial term ending in January 2010 and a one-year automatic renewal term thereafter. The nitrocellulose used in the test is also provided by a single contract supplier, under a supply agreement with a five year term ending in 2009.



OraSure Technologies, Inc.

diagnostic solutions for the new millennium

OraQuick® *ADVANCE*™ Rapid HIV-1/2 Antibody Test, the first and only U.S. Food and Drug Administration ("FDA") approved and CLIA (Clinical Laboratory Improvements Amendments Act of 1988) waived rapid point-of-care test that provides accurate results for both HIV-1 and HIV-2 in 20 minutes, using oral fluid, finger-stick or venipuncture whole blood or plasma specimens.

Attached are copies of SOP's SC003 and SOP SC004 which detail OraSure's procedures for Qualifying Vendors and Evaluating Vendors. The attached SOP's demonstrate that OraSure does not discriminate and that vendors are chosen and evaluated based on the quality of product and the quality of service that they are able to provide.

If you require additional information, please contact me at (916) 782-3119.

Regards,

Patricia Reis

Patricia Reis
Contract Manager

Cc: Paul LaKosky
Maribel Valdez
Tom Pavlowski
Melissa Hayes

220 East First Street • Bethlehem, Pennsylvania 18015-1360
Phone 610-882-1820 • Fax 610-882-1825
www.orasure.com

1. DOCUMENT APPROVAL

Functional Approval / Date	Document Owner / Date	Quality Assurance / Date
9/29/05	29 Sep 2005	04oct 2005

2. PURPOSE/SCOPE

The objective of this procedure is to facilitate maintenance and improvement of product quality by establishing a program for qualifying vendors and services for product.

3. RESPONSIBILITIES

Quality Assurance	To determine the disposition of a nominated vendor for high risk status. To conduct vendor site visits, facilitate corrective action and continuous improvement, as required.
Purchasing	To present a vendor survey for completion by the vendor; to communicate specifications to the vendors; to initiate and facilitate the completion of Purchasing Agreements when applicable; to assist in vendor site visits as required.

4. DEFINITIONS

Definitions of terminology used in this procedure are consistent with definitions found in SOP SC006.

5. DOCUMENTATION

5.1 Required Documents

WI QM035	Change Control
SOP QM005	Signature Authority for Quality Documents
SOP QM057	Supplier Audit Procedure
SOP SC001	Requesting and Assigning Part Numbers
SOP SC003.F1	Vendor Qualification Survey
SOP SC004	Vendor Performance Evaluation Procedure
SOP SC006	Purchasing Controls
SOP DD001	Design Control Procedure
WI SC001	Registration of Consultants, Contractors and Service Providers
WI SC007	Maintaining Purchasing Files (AVL, ACL and Vendor Files)

5.2 References/Standards

As referenced in the Company's Quality System Manual

6. PROCEDURE

6.1 Introduction/Preliminary Operations

6.1.1 See SOP SC006 for overview of Purchasing Controls.

6.1.2 Vendor requirements are established in a material specification or in a service contract.

6.1.3 Vendor Classification

6.1.3.1 The vendor class is the same as the material classification (assigned according to SOP SC001).

6.1.3.2 If a vendor provides more than one classification of materials, the Vendor Class is the same as the highest material classification number.

6.1.3.3 Contractors, service providers and consultants do not have a vendor classification.

6.1.4 Vendor class codes (as applied according to SOP SC006) distinguish requirements for qualification.

- Class 1 vendors do not require formal qualification and can be approved by Purchasing. These are not included on the AVL.
- Class 2 and 3 vendors require a completed Vendor Qualification Survey (SOP SC003.F1).
- Class 4 vendors require a completed Vendor Qualification Survey and a site audit per SOP QM057.

6.1.5 Service contractors require that a license or certification and proof of liability insurance be provided. Copies of methods, procedures, standards, etc. are provided/listed in the contract, if applicable.

6.1.6 Vendor performance is evaluated according to SOP SC004.

6.2 Vendor Qualification

6.2.1 Class 2, 3 and 4 Materials Procurement for Product

6.2.1.1 The Vendor Qualification Survey is mailed to the vendor with the proper enclosures:

6.2.1.1.1 Class 2, 3 and 4 vendors receive a "Letter to all Vendors" preceding the qualification. Appendix 1 includes the context that is printed on letterhead.

6.2.1.1.2 Class 4 vendors also receive a "Letter to Class 4 Vendors" as a second page to the "Letter to All Vendors". Appendix 2 includes the context that is printed on letterhead.

6.2.1.2 For Class 4 vendors, a site audit is scheduled.

6.2.1.3 The vendor is deemed qualified when the following has been completed:

6.2.1.3.1 A completed Vendor Qualification Survey is received and accepted by Purchasing and QA. See Section 6.3 for specific requirements.

6.2.1.3.2 For Class 4 vendors, no corrective actions are outstanding from the site audit.

6.2.1.4 Once the vendor has been added to the incoming inspection document according to WI QM035, the AVL is revised according to WI SC007.

6.2.2 Service Procurement

6.2.2.1 Service providers are registered according to WI SC001.

6.2.2.2 Once the service provider has met requirements in WI SC001, they are considered qualified and can be added to the ACL according to WI SC007.

6.3 Vendor Qualification Survey

6.3.1 Upon receipt of the survey, Purchasing reviews it to confirm that it has been completed according to the requirements outlined in Appendix 1.

6.3.1.1 If it has not been completed, Purchasing coordinates with the vendor until the survey is completed.

6.3.1.2 If it has been completed, Purchasing schedules a meeting with a member of QA to determine disposition.

6.3.2 Qualification disposition is determined by Purchasing and QA. The survey is reviewed and disposition determined.

- Accept – This box is marked if the information is acceptable and no further action is required.
- Reject – This box is marked if the vendor is unacceptable. Reasons are documented in the Comments section.
- Site Audit – If it is deemed that a site audit is required, this box is marked and QA schedules the audit.
- Additional Action – If additional action or more information is required from the vendor, this box is marked and the action(s) is outlined.

6.3.2.1 If additional information is provided as a result of "Additional Action" or "Site Audit" the survey and supplemental information may be reviewed according to this section.

6.3.2.2 For cases of "Reject" disposition, Materials Management will notify vendor of results in writing of removal from AVL. Any new request to use rejected vendor requires a site audit for qualification according to Section 6.2.

6.3.3 Once disposition is determined, the vendor classification is assigned and the survey is initialed and dated by the people determining disposition.

6.4 Qualification of Existing Vendors

6.4.1 Qualify existing vendors through the acceptance of the historical performance of components or services supplied by the vendor.

6.4.2 The following criteria for acceptance based on historical performance includes:

- Incoming inspection records which demonstrate the vendor's ability to comply with component requirements
- The ability of the vendor to correct failures, respond to problems, and cooperate to resolve technical difficulties
- Ordered quantities have been supplied on a consistent basis and delivery has been on schedule
- If applicable, vendor audits have been favorable, vendor response to an audit was adequate, and improvements were apparent.

6.5 Approved Vendor List

6.5.1 Vendors who provide materials for product are included on the AVL.

6.5.2 The following information is included and updated in the AVL:

- Vendor Name or Manufacturer Name
- Vendor or Manufacturer Class
- Commodity code(s)
- Date Qualification Survey completed, if applicable
- Last audit date, if applicable
- Most recent performance rating, and month and year rating is established

6.5.3 Purchasing maintains the AVL according to WI SC007.

6.6 Approved Contract List

6.6.1 Service providers/contractors who support the Quality System are included on the ACL.

6.6.2 The following information is included in the ACL upon receipt of contractor form.

- Company name
- Service provided
- Expiration date on contract if applicable
- Performance Rating, if applicable

6.6.3 Purchasing maintains the ACL according to WI SC007.

Appendix 1

Example of Letter to All Vendors

Date

(type recipient's address here)

Attention: QA Manager

Dear Sir or Madam:

OraSure Technologies, Inc. is a manufacturer of medical devices and *in vitro* diagnostics. To satisfy our Purchasing Quality System Requirements, and to develop a better business relationship between our two companies, we are formally qualifying all OraSure Technologies, Inc. vendors.

To be qualified as an OraSure Technologies, Inc. vendor, we need you to complete, sign and return the enclosed Vendor Qualification Survey. Please use black or blue ink. Insert N/A to those questions that do not apply. Please return by U.S. mail within two weeks of the date received.

My business card is enclosed with my telephone, fax, and email address. Please feel free to contact me with any questions or inquiries you may have. Thank you in advance.

Best regards,

OraSure Technologies, Inc.

(type name here)

(type job title here)

Appendix 2

Example of Letter to Class 4 Vendors

Date

(type recipient's address here)

Attention: QA Manager

Dear Sir or Madam:

You provide critical material to the process of OraSure Technologies Inc. As a provider of a critical material, please enclose the following documentation in addition to your Qualification Survey.

1. A copy of your Quality Manual.
2. A copy of ISO, GMP, or other recognized quality system organization, if available.
3. Documentation or statement describing your Formal Change Controls and means of notifying customers of changes to processes, facilities, equipment or raw materials that may affect the quality of the product you provide.
4. A business card or contact information to whom we may schedule an on-site audit.

Sincerely,

OraSure Technologies, Inc.
(type name here)
(type job title here)

OraSure Technologies, Inc. – Vendor Qualification Survey

1. VENDOR INFORMATION

1.1 General Information

Vendor Name:	Subsidiary/Division of:
Dun and Bradstreet Number:	Gross Sales for Prior Year:
Address:	
City:	State: Zip:
Telephone:	FAX:
Sales Contact:	Telephone:
Quality Assurance Contact:	
Telephone:	FAX:
Type of Facility: ☐ Manufacturing ☐ Service ☐ Consultant ☐ Distributor ☐ Other _____	
How long has your company been in business?	
How many people does your company employ?	

1.2 General Ordering Terms

f.o.b.:	Terms of Payment:
Types of Freight Allowed (Full, Pre-paid, Collect, etc.):	

1.3 Customers/References

Company Name/Contact Name	Contact phone number

1.4 List manufacturing done by outside entities on materials being procured by OraSure Technologies (subassembly, packaging, subcontracting, etc.)

1.	
2.	
3.	

1.5 Insurance

Does your company have Liability Insurance?	
Insurer:	Provide Certificate of Insurance:

OCT 13 2005

1.6 Inspections

Have local, state or federal agencies inspected Manufacturer within the last two years?

☐ Yes ☐ No, If Yes when: _____

Name of Agencies	Recalls Involved?	Write-ups?

Comments:

2. MANAGEMENT RESPONSIBILITY

2.1	Has management defined and documented a corporate policy on quality?	☐ Yes	☐ No	☐ N/A
2.2	Is a Quality Policy Manual maintained and utilized throughout the company? Date of First Issue: _____ Date of Last Review: _____ By Whom: _____	☐ Yes	☐ No	☐ N/A
2.3	Are policies and practices in compliance with all regulatory agency requirements?	☐ Yes	☐ No	☐ N/A
2.4	Is this policy communicated at all levels of the company?	☐ Yes	☐ No	☐ N/A
2.5	Is there a quality function or well-defined organization that provides customer advocate guidance to the total organization and is this position fully supported by management?	☐ Yes	☐ No	☐ N/A
2.6	Do the individuals in the quality function have sufficient organizational freedom and independence to control processing, delivery and installation of nonconforming product until unsatisfactory conditions have been corrected?	☐ Yes	☐ No	☐ N/A
2.7	Is management review carried out regularly to ensure suitability, compliance and effectiveness of the quality systems actions (Rejection levels, complaints, corrective actions, and recalls)? If yes, date of last review: _____ By Whom: _____	☐ Yes	☐ No	☐ N/A
2.8	Are records maintained of these reviews? If so, for how long? _____	☐ Yes	☐ No	☐ N/A

3. QUALITY ASSURANCE

3.1	Is there a Quality Assurance manual?	☐ Yes	☐ No	☐ N/A
3.2	Is manual available for review or provided to OraSure Technologies?	☐ Yes	☐ No	☐ N/A
3.3	Is there a system for revision of quality procedures?	☐ Yes	☐ No	☐ N/A
3.4	Is a corrective action system in place?	☐ Yes	☐ No	☐ N/A
3.5	Is an internal audit system in place?	☐ Yes	☐ No	☐ N/A
3.6	Are current specifications for all OraSure Technologies products on file?	☐ Yes	☐ No	☐ N/A
3.7	Are MSDS sheets on file for all OraSure Technologies products?	☐ Yes	☐ No	☐ N/A
3.8	Are documented procedures in place and followed for product specification changes?	☐ Yes	☐ No	☐ N/A
3.9	Are documented procedures in place and followed to isolate off-spec materials?	☐ Yes	☐ No	☐ N/A
3.10	Can QA overrule Sales and Management on questions of what products can be shipped to OraSure Technologies?	☐ Yes	☐ No	☐ N/A
3.11	Are documented procedures in place and followed for lot retains? How long are retains maintained? _____	☐ Yes	☐ No	☐ N/A
3.12	Are documented procedures in place and followed for quality control practices?	☐ Yes	☐ No	☐ N/A
3.13	Are quality control plans, inspections, testing techniques and instrumentation updated as needed?	☐ Yes	☐ No	☐ N/A
3.14	Is the facility ISO9000 certified? If yes, date of certification: _____ Enclose copy of certification.	☐ Yes	☐ No	☐ N/A
3.15	Is the facility QS9000 certified? If yes, date of certification: _____ Enclose copy of certification.	☐ Yes	☐ No	☐ N/A
3.16	Is the facility FDA registered? If yes, Registration number: _____	☐ Yes	☐ No	☐ N/A
3.17	Is the facility FDA inspected? Date/Results of last inspection: _____	☐ Yes	☐ No	☐ N/A
3.18	Do operations adhere to current Good Laboratory Practice (GLP) requirements?	☐ Yes	☐ No	☐ N/A
3.19	Do operations adhere to current Good Manufacturing Practice (GMP) requirements?	☐ Yes	☐ No	☐ N/A

OCT 13 2005

4. DOCUMENT CONTROL

4.1	Are procedures established and maintained to control all documents and data that relate to requirements?	☐ Yes	☐ No	☐ N/A
4.2	Are these documents reviewed and approved for adequacy by authorized personnel prior to issue?	☐ Yes	☐ No	☐ N/A
4.3	Is there a procedure to create, approve and change documentation?	☐ Yes	☐ No	☐ N/A
4.4	Are changes to documents reviewed and approved by the same functions/organization that performed the original review and approval?	☐ Yes	☐ No	☐ N/A
4.5	Are specific changes being made clearly identified in the document or in an appropriate attachment?	☐ Yes	☐ No	☐ N/A
4.6	Is a master list or database in place that identifies current revisions of documents in order to eliminate use of non-applicable documents?	☐ Yes	☐ No	☐ N/A
4.7	Are current revisions of appropriate documents available at all essential operational locations?	☐ Yes	☐ No	☐ N/A
4.8	Is a documented procedure in place that ensures prompt removal of obsolete documents and enactment of revisions from all points of issue or use?	☐ Yes	☐ No	☐ N/A
4.9	Is there a procedure for reviewing documents for applicability/accuracy in a specified time period?	☐ Yes	☐ No	☐ N/A

5. PURCHASING

5.1	Are procedures in place that require suppliers capabilities be reviewed and approved before they are used?	☐ Yes	☐ No	☐ N/A
5.2	Are procedures in place ensuring vendors are selected based on demonstrated capability, performance, and quality system conformance?	☐ Yes	☐ No	☐ N/A
5.3	Do purchasing documents contain data clearly describing product or service ordered?	☐ Yes	☐ No	☐ N/A
5.4	Are specifications, drawings, inspection instructions or other relevant data attached to all purchasing documents?	☐ Yes	☐ No	☐ N/A
5.5	Are purchasing documents reviewed and approved for adequacy and correctness of specified requirements prior to release?	☐ Yes	☐ No	☐ N/A
5.6	Are requirements defined, communicated, and updated to ensure supplier understands expectations and responsibilities?	☐ Yes	☐ No	☐ N/A
5.7	Does a supplier performance/rating system exist?	☐ Yes	☐ No	☐ N/A
5.8	Are vendors surveyed periodically? If yes, how often: _____ By whom: _____	☐ Yes	☐ No	☐ N/A
5.9	Is lost, damaged or unsuitable product recorded and reported to vendors?	☐ Yes	☐ No	☐ N/A

OCT 13 2005

6. PRODUCTION/PROCESS CONTROL

6.1	Do written protocols exist for all manufacturing processes?	☐ Yes	☐ No	☐ N/A
6.2	Are changes to protocols made only under a formal change control procedure?	☐ Yes	☐ No	☐ N/A
6.3	Are all production processes formally qualified and validated before release?	☐ Yes	☐ No	☐ N/A
6.4	Are records maintained of qualification procedures?	☐ Yes	☐ No	☐ N/A
6.5	Are records maintained of validation procedures?	☐ Yes	☐ No	☐ N/A
6.6	Are batch records maintained for each production run?	☐ Yes	☐ No	☐ N/A
6.7	Are batch production records available to OraSure Technologies for review?	☐ Yes	☐ No	☐ N/A
6.8	Are production runs identified by lot or serial numbers?	☐ Yes	☐ No	☐ N/A
6.9	Are databases or records maintained of lot or serial number traceability?	☐ Yes	☐ No	☐ N/A
6.10	Is inspection conducted at critical points in each production run?	☐ Yes	☐ No	☐ N/A
6.11	Are these inspections included as part of each batch record?	☐ Yes	☐ No	☐ N/A
6.12	Do batch records contain protocol revision information?	☐ Yes	☐ No	☐ N/A
6.13	Are there adequate environmental control procedures in each production area?	☐ Yes	☐ No	☐ N/A
6.14	Are these procedures documented?	☐ Yes	☐ No	☐ N/A
6.15	Do procedures exist for the handling, storage, and disposition of non-conforming materials?	☐ Yes	☐ No	☐ N/A
6.16	Are customers informed of changes made to production processes and raw materials and, when required, processed with customer approval prior to the changes?	☐ Yes	☐ No	☐ N/A
6.17	How is a lot number/batch defined? What is the lot numbering system?	☐ Yes	☐ No	☐ N/A

7. QUALITY CONTROL

7.1	Are procedures in place to prevent use of nonconforming product?	☐ Yes	☐ No	☐ N/A
7.2	Is the Inspection/Test status of materials readily identifiable?	☐ Yes	☐ No	☐ N/A
7.3	Are quality related records protected and stored to ensure easy access?	☐ Yes	☐ No	☐ N/A
7.4	Are procedures in place to govern the retention and storage of quality related records?	☐ Yes	☐ No	☐ N/A
7.5	Are quality-related activities periodically audited for conformance to written policies and procedures?	☐ Yes	☐ No	☐ N/A
7.6	Are results of Internal Audits discussed with participants and corrective actions instituted as necessary?	☐ Yes	☐ No	☐ N/A
7.7	Are results of internal audits reported to management?	☐ Yes	☐ No	☐ N/A

OCT 13 2005

7. QUALITY CONTROL (CONTINUED)

7.8	Are sampling plans used for product acceptance?	☐ Yes	☐ No	☐ N/A
7.9	Are customer complaints investigated, recorded and resolved by QA/QC departments?	☐ Yes	☐ No	☐ N/A
7.10	Are quality records made available to OraSure Technologies?	☐ Yes	☐ No	☐ N/A
7.11	Is incoming product not used until it has been inspected, analyzed and verified as to correctness and/or conformation to documented specifications?	☐ Yes	☐ No	☐ N/A
7.12	Is incoming product suitably quarantined to ensure it is not used prior to inspection?	☐ Yes	☐ No	☐ N/A
7.13	Is incoming product identified and recorded when it is released for emergency production needs, which will easily permit its immediate recall in case of nonconformance?	☐ Yes	☐ No	☐ N/A
7.14	Are records established and maintained which give evidence that products have passed inspection and/or tests in conformance with defined acceptance criteria?	☐ Yes	☐ No	☐ N/A
7.15	Are nonconforming products identified by labelling?	☐ Yes	☐ No	☐ N/A

8. CORRECTIVE ACTION

8.1	Are corrective action procedures established, documented, and maintained?	☐ Yes	☐ No	☐ N/A
8.2	Are all causes of nonconforming product and the corrective action necessary to prevent recurrence investigated?	☐ Yes	☐ No	☐ N/A
8.3	Are corrective action investigations and corrections performed in a timely and effective manner?	☐ Yes	☐ No	☐ N/A

9. HANDLING, STORAGE, PACKAGING, AND DELIVERY

9.1	Are documented procedures established and maintained for handling, storage, packaging, and delivery of product?	☐ Yes	☐ No	☐ N/A
9.2	Is the condition of stored product monitored or periodically checked?	☐ Yes	☐ No	☐ N/A
9.3	Is material packed, identified, labeled and marked to ensure correctness and compliance with specified requirements?	☐ Yes	☐ No	☐ N/A
9.4	Is material segregated (rejected, in-process, finished goods)?	☐ Yes	☐ No	☐ N/A
9.5	Are materials and finished products identified to ensure integrity of age and date control?	☐ Yes	☐ No	☐ N/A
9.6	Are products date coded?	☐ Yes	☐ No	☐ N/A
9.7	Are procedures in place to retrieve and remove nonconforming or expired products?	☐ Yes	☐ No	☐ N/A
9.8	Are products marked with shelf life or expiration dates?	☐ Yes	☐ No	☐ N/A
9.9	Are bar codes used to identify and control products?	☐ Yes	☐ No	☐ N/A
9.10	Are materials used on a first-in, first-out basis to minimize aging?	☐ Yes	☐ No	☐ N/A

OCT 13 2005

10. TRAINING

10.1	Are procedures and documentation established for identification of training needs and providing training of all personnel performing activities affecting quality during production and installation?	☐ Yes	☐ No	☐ N/A
10.2	Are personnel performing specific assigned tasks qualified on the basis of appropriate education, training, and/or experience, as required?	☐ Yes	☐ No	☐ N/A
10.3	Do job specifications/descriptions exist to outline these?	☐ Yes	☐ No	☐ N/A
10.4	Are records of training maintained? If yes, where? _____	☐ Yes	☐ No	☐ N/A
10.5	Are all personnel trained in sufficient detail to support key initiatives?	☐ Yes	☐ No	☐ N/A
10.6	Are training results properly evaluated and audited?	☐ Yes	☐ No	☐ N/A

11. FACILITIES

11.1	Is all test, inspection, and measuring equipment that may affect product quality identified, calibrated, and adjusted at prescribed intervals against certified nationally recognized standards?	☐ Yes	☐ No	☐ N/A
11.2	Is a documented calibration procedure that includes: equipment type, identification number, location, frequency of checks, check method, acceptance criteria and the action to be taken when results are satisfactory?	☐ Yes	☐ No	☐ N/A
11.3	Are records maintained documenting extent and frequency of checks? If yes, where? _____	☐ Yes	☐ No	☐ N/A
11.4	Are environmental conditions suitable for the calibrations, inspections, measurements, and tests performed?	☐ Yes	☐ No	☐ N/A
11.5	Is all test, calibration, and certification documentation maintained in a suitable database location?	☐ Yes	☐ No	☐ N/A
11.6	Are HVAC requirements adequately defined and documented?	☐ Yes	☐ No	☐ N/A
11.7	How often are HVAC systems monitored or inspected?	☐ Yes	☐ No	☐ N/A
11.8	Are air classes periodically tested for all areas?	☐ Yes	☐ No	☐ N/A
11.9	Are water classes periodically tested? If yes, how often? _____	☐ Yes	☐ No	☐ N/A
11.10	Are compressed gases used and required purities defined?	☐ Yes	☐ No	☐ N/A
11.11	Are procedures defined and documented for the disposal of nonconforming product?	☐ Yes	☐ No	☐ N/A
11.12	Are housekeeping procedures defined and documented?	☐ Yes	☐ No	☐ N/A
11.13	Are wastes handled and disposed of in a documented and appropriate manner?	☐ Yes	☐ No	☐ N/A
11.14	Does an established facility safety manual and program exist?	☐ Yes	☐ No	☐ N/A

Vendor Representative Signature/Date:

Section completed by OraSure Technologies only

Disposition: ☐ Accept ☐ Reject ☐ Site Audit ☐ Additional Action

Comments:

Vendor Classification: ☐ Class 2 ☐ Class 3 ☐ Class 4

Disposition By/Date:

Purchasing representative:	QA representative:

OCT 13 2005

1. DOCUMENT APPROVAL

Functional Approval	Document Owner	Quality Assurance
6/1/05	6/1/05	03 Jun 05

2. PURPOSE/SCOPE

To establish the criteria, procedure for monitoring, evaluating, and assignment of rating for vendor performance.

This procedure applies to all Class 2, 3 and 4 qualified vendors of goods and services whose performance could impact the performance and safety or efficacy of an inventory controlled product.

3. RESPONSIBILITIES

Purchasing	Complete and review vendor performance; communicate results of vendor performance. Review high-risk nominations, and determine action items and assignment.
Quality Assurance	Provide quality related support in completing the Vendor Performance Evaluation Worksheet; provide a summary of Nonconformance Reports. Review high-risk nominations, and determine action items and assignment.
Development	Provide technical support in evaluating services performed and product performance. Review high-risk nominations, and determine action items and assignment.
Operations	Review high-risk nominations, and determine action items and assignment.

4. DEFINITIONS

Definitions of terminology used in this procedure are consistent with definitions found in SOP SC006.

5. DOCUMENTATION

5.1 Required Documents

SOP CP004	Nonconformance Reporting
SOP QM057.F5	Supplier Audit Finding Report
SOP QM025	Quality Records: Identification, Access, Storage and Distribution
SOP QM027	Quality Records: Documentation, Correction, Review and Approval
SOP SC004.F1	Vendor Performance Evaluation Worksheet
SOP SC004.F2	High Risk Vendor Form
SOP SC006	Purchasing Controls
WI SC015	Procurement Using the MAS 200 System
Vendor File	

5.2 References/Standards

References/Standards referenced in Section 6.0 of the Company's Quality System Manual

6. PROCEDURE

6.1 Introduction/Preliminary Operations

6.1.1 See SOP SC006 for overview of Purchasing Controls.

6.1.2 Conduct a performance evaluation of vendors at least annually. Conduct additional or more frequent evaluations when:

- The vendor has provided inadequate standards of quality and/or service.
- The vendor's rating is a "1" in any one category or has been nominated for high risk.
- The vendor is being re-evaluated for upgrade following completion of identified corrective actions.
- The vendor has been determined to be high risk.

6.2 Vendor Performance Evaluation Worksheet Criteria:

6.2.1 Order Delivery Evaluation - Includes on-time delivery, quantity accuracy, required documentation, suitable or specified packaging and proper shipping documents. The ideal performance in this area would be orders received on time, without overage or underage, correct documentation and proper packaging, labeling and inclusion of correct shipping documents. Services would be started and ended on time, with proper documentation and report generation as required.

6.2.2 Product or Service Quality Evaluation - Includes quality acceptance or rejection with in depth review of quality problems and the vendor's response to them (if any material or service has been identified as discrepant or rejected). The ideal performance in this area would be no discrepant material or discrepancies in service. The ideal response would be prompt investigation and resolution that includes rework/repair/replacement/credit and effective corrective action to prevent re-occurrence.

6.2.3 Customer Service Evaluation - Includes order placement and confirmation, response to requests for information, and notification of changes in order status. The ideal performance in this area would exhibit prompt, courteous and professional response.

6.3 Changes of Qualification Status

6.3.1 The vendor's qualification status applies to the manufacturing site, production process, product component requirements, and end-use of the product.

6.3.2 Re-evaluate the qualification when a change in one or more of the above parameters occurs.

6.4 Worksheet Completion (SOP SC004.F1):

6.4.1 Using SOP SC004.F1 as a guide, review qualified vendors currently on the AVL.

6.4.1.1 Obtain a summary of Nonconformance Reports (SOP CP004) regarding the material and/or vendor since the last evaluation period or within one year.

6.4.1.2 For Class 4 vendors, obtain audit information (SOP QM057.F5).

6.4.1.3 Obtain memo entries from the inventory control system.

6.4.2 After gathering and reviewing data for the vendor under evaluation, complete each section of SOP SC004.F1.

6.4.3 Select the rating scale that most closely matches the vendor's performance for each category.

6.4.4 Add comments in the space provided to justify or clarify the rating.

6.4.5 Assign the vendor a score for each category, Order Delivery, Product and Service and Customer Service.

6.4.6 Total the scores

6.4.6.1 Vendors with scores totaling 21 – 25 are deemed "Excellent".

6.4.6.2 Vendors with scores totaling 13 – 20 are deemed "Acceptable".

6.4.6.3 Vendors with scores totaling 12 or below or have a "1" rating in any of the categories are deemed "High Risk". The steps outlined in Section 6.5 are completed in addition to steps 6.4.7 – 6.4.9.

6.4.7 This score is entered on the AVL in the assigned columns.

6.4.8 This score is also noted in inventory control system using WI SC015, Creating or Maintaining Vendor Memos.

6.4.9 Include any pertinent information that supports the evaluation with the Vendor Performance Evaluation Worksheet:

6.4.10 Notify the vendor of their performance evaluation summary ratings. (The period covered by the summary is one year or since the last evaluation.)

6.5 High Risk Nomination

6.5.1 Completing SOP SC004.F2 - The High Risk Vendor Form is completed to nominate a vendor for High Risk status.

6.5.1.1 Section 1 is completed and transferred to Purchasing.

6.5.1.2 Section 2 is completed by Purchasing and QA.

6.5.1.3 Disposition is determined by an Area Approval Team member from QA, Operations and Development, and Purchasing.

- A risk analysis is performed to determine appropriate course of action(s) and due date(s) for the completion of the action(s).

6.5.1.4 If it is agreed that the vendor qualification status is to be changed, the AVL is modified according to WI SC007 and perform steps as outlined below.

6.5.2 Notify "High Risk" vendors of their rating in writing. Place a copy of the letter in vendor file.

6.5.3 If the vendor can demonstrate corrective action to issues identified, they may solicit reevaluation and reconsideration.

6.6 Recordkeeping

6.6.1 Post records in the vendor file consistent with SOP QM027 and SOP QM025.

Doc. Title: Vendor Performance Evaluation Worksheet

Vendor Name:

Performance Criteria	Rating Scale	Vendor Rating (circle rating)	Comments
Order Delivery			
• Delivery % on Time	0-20%	1	
	21-49%	2	
	50-59%	3	
	60-79%	4	
	80-100%	5	
• Quantity Delivered o Product o Order completeness	0-20%	1	
	21-49%	2	
	50-59%	3	
	60-79%	4	
	80-100%	5	
• Documentation Control o Product Shipping, Labeling o Packing slips, C of A's & C's o Included in shipment o Labeling accuracy	Poor	1	
	Inconsistent	2	
	Fair	3	
	Good	4	
	Excellent	5	
Product & Services			
• Response to Corrective Action Follow-up	Poor	1	
	Inadequate	2	
	Adequate	3	
	Good	4	
	Excellent	5	
Customer Service			
• Order Placement, Confirmation	Poor	1	
	Inconsistent	2	
	Fair	3	
	Good	4	
	Excellent	5	
Total	Excellent	21 – 25	
	Acceptable	13 – 20	
	High Risk	< 12 or a "1" in one of the categories	

Completed By/Date: _____

SECTION 1

Vendor nominated for high risk status:
Justification:
Is there an alternate source? ☐ No ☐ Yes If "yes," identify the alternate vendor's name:
Replacement plan:
Completed By/Date:

SECTION 2

Actions:	Action Type	CAPA Category	Action Assignee	Action Item #
1.	☐ Corrective ☐ Preventive	☐ CAPA Level I ☐ CAPA Level II ☐ CAPA Level III		
2.	☐ Corrective ☐ Preventive	☐ CAPA Level I ☐ CAPA Level II ☐ CAPA Level III		
3.	☐ Corrective ☐ Preventive	☐ CAPA Level I ☐ CAPA Level II ☐ CAPA Level III		

Comments:

Disposition: ☐ Agree ☐ Disagree (justification in Comments section)
Quality Assurance:
Operations:
Development:
Purchasing:

Abbott
A Promise for Life

OraSure Technologies, Inc.
diagnostic solutions for the new millennium

OraQuick ADVANCE HIV-1/2 Distribution Rights and Assigned Market Segments

On February 11, 2005, OraSure Technologies, Inc. and Abbott Laboratories announced an agreement for the distribution of OraSure Technologies' OraQuick® *ADVANCE*™ rapid antibody test for the detection of antibodies to HIV-1 and HIV-2. Under the terms of the distribution agreement, Abbott was appointed as exclusive distributor of the OraQuick® *ADVANCE*™ HIV-1/2 test for hospitals and reference laboratories and as a non-exclusive distributor to physician offices in the United States. The following is intended to provide some clarity to the terms of the agreement and distribution rights given to Abbott.

Exclusive Distribution Rights

Abbott has been granted exclusive rights to distribute OraQuick® *ADVANCE*™ HIV-1/2 devices and controls to hospital customers and reference laboratories located in the United States. The term "hospital" generally means an institution that meets all of the following:

- An acute care institution that is licensed and operated as a hospital,
- An institution that is accredited as a hospital by the Joint Commission on Accreditation of Healthcare Organizations or the Bureau of Hospitals of the American Osteopathic Association and, in each case, is certified as a hospital provider under Medicare,
- An institution that provides for the care and treatment of resident in-patients for a variety of medical conditions, both surgical and non-surgical, and
- An institution that provides treatment under the supervision of a staff of physicians with 24-hour per day nursing care and internal laboratory services

A hospital does not include any affiliated clinic or treatment center or physician office or physician practice unless that clinic, treatment center, physician office or physician practice is wholly-owned by an institution that is within the definition of hospital.

The term "reference laboratory" means commercial reference laboratories where rapid point-of-care testing for HIV-1 and HIV-2 is performed within a laboratory for outside customers and where tests are not resold or otherwise distributed by the laboratory.

In addition, Abbott has been appointed as an exclusive distributor for U.S. government hospitals purchasing OraQuick® *ADVANCE*™ HIV-1/2 from the GSA. In this capacity, Abbott may sell to U.S. government hospitals under the terms of OraSure's Federal

Supply Schedule, including the price for OraQuick® *ADVANCE*™ HIV-1/2 devices and controls in that Schedule.

Under the agreement, Abbott is not permitted to use a subdistributor or agent to sell directly to hospitals or reference laboratories.

Non-Exclusive Appointment

Abbott has been granted the non-exclusive right to distribute OraQuick® *ADVANCE*™ HIV-1/2 devices and controls to physicians' offices located in the United States. Physicians' offices include general practitioners, internists, obstetricians, gynecologists, pediatricians and other licensed physicians in the United States. This segment would not include any physicians in offices or practices that are wholly-owned by a hospital or that practice in the public health segment.

Abbott is permitted to utilize subdistributors and agents to service the physicians' office segment, under the terms of the agreement.

Special Customer Exclusions

Abbott's distribution rights are solely for hospitals, reference laboratories and physicians' offices. That means that neither Abbott nor its subdistributors or agents are permitted to sell OraQuick® *ADVANCE*™ HIV-1/2 devices or controls to any other customer.

Abbott is specifically excluded from selling into the public health segment of the market in the United States. This segment of the market includes community-based organizations, AIDS service organizations, county public health departments, correctional and criminal justice departments (including county, state, and federal drug courts, probation centers, departments of correction, detention centers, jails and prisons), substance abuse clinics, sexually-transmitted disease clinics, substance abuse centers, student health centers and clinics, abortion clinics, family planning clinics, planned parenthood clinics and other similar organizations or entities. However, to the extent a clinic or treatment center is wholly-owned by a hospital, Abbott would have exclusive rights to distribute to that entity as if it were a hospital customer.

Please feel free to contact us with any questions regarding the above.

Troy Smith
Rapid Products Manager
Abbott Laboratories
847-937-7199

Patti Davis
Director of Marketing, Infectious Disease
OraSure Technologies
610-882-1820 ext. 3410

DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

SUBSTANCE ABUSE (SA), HIV, & HEPATITIS PREVENTION FOR MINORITY POPULATIONS & MINORITY REENTRY POPULATIONS IN COMMUNITIES OF COLOR (SP 05-001)

SHORT TITLE: *Minority SA/HIV/Hep Strategic Prevention Framework (SPF)*

ANNOUNCEMENT TYPE: INITIAL

Catalogue of Federal Domestic Assistance (CFDA) No. 93.243

Key Dates:

Application Deadline	**Applications are due by March 17, 2005.**
Intergovernmental Review (E.O. 12372)	**Letters from State Single Point of Contact (SPOC) are due no later than 60 days after application deadline.**
Public Health System Impact Statement (PHSIS)/SSA Coordination	**Applicants must send the PHSIS to appropriate State and local health agencies by application deadline. Comments from Single State Agency are due no later than 60 days after application deadline.**

Beverly Watts Davis
Director, Center for Substance Abuse Prevention
Substance Abuse and Mental Health
Services Administration

Charles G. Curie, M.A., A.C.S.W.
Administrator
Substance Abuse and Mental Health
Services Administration

TABLE OF CONTENTS

TABLE OF CONTENTS (CONTINUED)

I. FUNDING OPPORTUNITY DESCRIPTION

1. INTRODUCTION

As authorized under Section 516 of the Public Health Service Act, the Substance Abuse and Mental Health Services Administration (SAMHSA) Center for Substance Abuse Prevention (CSAP) announces the availability of funds for its *Substance Abuse (SA), HIV, & Hepatitis Prevention for Minority Populations and Minority Reentry Populations in Communities Of Color* Initiative.

This initiative supports an array of activities to assist grantees in building a solid foundation for delivering and sustaining effective substance abuse prevention and related services. Specifically, the program aims to engage community-level domestic public and private non-profit entities to prevent and reduce the onset of SA, and transmission of HIV and hepatitis among minority populations and minority reentry populations in communities of color disproportionately affected by SA, HIV/AIDS, and/or hepatitis.

While grantees will have substantial flexibility in designing their grant projects, all are required to base their projects on the five steps of SAMHSA's Strategic Prevention Framework (SPF) to build a service capacity specific to SA, HIV, and hepatitis prevention services.

2. EXPECTATIONS

Grantees will be funded for up to five years to implement SAMHSA's SPF in partnership with other State and community-level organizations. The Minority SA/HIV/Hep SPF program provides an effective prevention process, a direction and a common set of goals, expectations and accountabilities to be adopted and integrated on the community level. Grantees are required to provide leadership and coordination on the planning and implementation of the SPF project that targets minority populations and minority reentry populations in communities of color with high prevalence of SA, HIV/AIDS, and hepatitis.

2.1 ALLOWABLE ACTIVITIES

Moving SAMHSA's SPF from vision to practice is a strategic process that community stakeholders must undertake in partnership. The Minority SA/HIV/Hep SPF grant funds must be used primarily to support the implementation of the following **required** five steps of the SPF:

1. **Conduct a community needs assessment:**
   Grantees are required to conduct an in-depth community (e.g., tribal jurisdictions, towns, cities, counties) needs assessment in areas reporting high rates of SA, HIV/AIDS, and hepatitis cases through collection and analysis of epidemiological data, that includes the following:
   - Assessment of the magnitude of SA, HIV, and hepatitis in the catchment area,
   - Assessment of risk and protective factors associated with SA, HIV, and hepatitis in the catchment area,

- Assessment of the number of individuals at risk for HIV and hepatitis due to substance abuse
- Assessment of the number of post-incarcerated individuals at risk for SA, HIV and hepatitis reentering minority communities
- Assessment of community assets and resources
- Identification of gaps in services and capacity
- Assessment of readiness to act
- Identification of priorities based on the epidemiological analyses, including the identification of target populations of greatest need to implement the SPF and specification of baseline data.

In order to complete the community needs assessment, grantees must form and manage a workgroup with key stakeholders or work with an existing epidemiological workgroup. The needs assessment should be broad enough to encompass the entire specified catchment area for the proposed project. If the grantee is already engaged in a needs assessment effort, they should work with a local or State epidemiological workgroup (i.e. SAMHSA's SPF State Incentive Grant Epidemiological Workgroup) to enhance and supplement the current process and its findings. SAMHSA expects that these data collection efforts will support on-going monitoring and evaluation throughout the five-year project period, as described in Step 5 (below). Applicants must be prepared to serve minority populations of greatest need, as determined in the needs assessment.

NOTE: Applicants who have recently completed a comprehensive community needs assessment should submit a copy of their needs assessment in Appendix 5 of their application. Successful applicants will be required to further conduct a needs assessment on reentry populations, if the focus on reentry populations is not reflected in the submitted documentation. Successful applicants with an approved needs assessment focused on both target populations may be able to receive up to five years of funding to carry out Steps 2-5 of the SPF.

2. **Mobilize and/or build capacity to address SA, HIV, and hepatitis prevention needs:**

It is important for grantees to develop and enhance local capacity and mobilize community resources in order to implement effective programs, practices, and strategies to prevent and reduce the onset of SA, and transmission of HIV and hepatitis among reentry populations and communities of color. The Minority SA/HIV/Hep SPF grantees must, therefore, engage in activities that include but are not limited to: training community stakeholders and service providers; forming linkages to care; and leveraging resources for program sustainability. Grantees are required to demonstrate planning and coordination of services with a local or State epidemiological workgroup (identified through their Single State Agency). To ensure coordination and successful implementation of the Minority SA/HIV/Hep SPF project, grantees are also required to collaborate and coordinate with key stakeholders or representatives from State and community level programs, including those listed below where applicable:

- Centers for Disease Control and Prevention's (CDC) National Center for HIV/AIDS, STD, TB Prevention's (NCHSTP) HIV Prevention Community Planning Groups
- Health Resources and Services Administration (HRSA) Ryan White Planning Councils
- Juvenile and adult criminal justice, correctional, parole systems and reentry programs
- National Immunization Program, and HIV/AIDS CDC funded projects
- Hepatitis prevention programs
- American Indian/Alaska Native tribal councils, Tribal community- based organizations, Tribal governments, and Indian Health Service-funded programs
- Support service programs for persons with HIV/AIDS and other infectious diseases

3. **Develop a Comprehensive Strategic Plan:**
Grantees are expected to develop a strategic plan resulting from the documented community needs assessment that articulates a vision for the Minority SA/HIV/Hep SPF project. Grantees must plan to provide culturally appropriate services to minority populations of greatest need, as determined by the needs assessment. The comprehensive strategic plan must be based on documented needs, the identified evidence-based practice for minority and reentry populations, resources/strengths, set measurable objectives and include the performance measures and baseline data against which progress will be monitored. The strategic plans must also focus on the need to provide hepatitis screening and linkages to services that provide immunization for hepatitis A or B. ***Assigned CSAP Project Officers must approve the strategic plan, which includes identified evidence-based practices, before implementation activities can begin.***

4. **Implement evidence-based prevention programs and infrastructure development activities:**
Grantees are expected to implement evidence-based behavioral interventions to prevent and reduce the onset of substance abuse and the transmission of HIV and Hepatitis in their local community of color with high prevalence of SA, HIV, and hepatitis, as determined through the needs assessment. Key services supported by the program's grant funds include:
   - Outreach to identify minority populations and reentry populations at high risk for SA and transmission of HIV and hepatitis.
   - Screening for SA, hepatitis*, and HIV (rapid HIV testing**)
   - Pre/Post SA and HIV counseling (before the administration of the rapid HIV test, during the waiting period for preliminary results and after preliminary results have been provided).
   - SA, HIV/AIDS, and hepatitis education and prevention interventions for at-risk minority and minority reentry populations, their significant other(s), and family members;
   - Referrals to appropriate medical treatment, counseling, and other supportive services for clients who are confirmed HIV positive; referrals to effective

counseling for persons who previously tested negative to decrease their risk of acquiring HIV.

- Referrals to hepatitis A and B immunization services.

* **Project funds may be used for Hepatitis screening and testing (e.g., Hepatitis A and B in MSM; Hepatitis B and C in injection drug users) but NOT for immunizations against hepatitis A or B.**

** OraQuick® ADVANCE Rapid HIV-1/2 Antibody Test kits, control kits, confirmatory kits, and confirmation laboratory services from OraSure Technologies, Inc. and will provide these products and services to qualified grantees at no cost. **To obtain SAMHSA's free rapid HIV test kits and free confirmation laboratory services, the Minority SA/HIV/Hep SPF grantees will be required to meet the following Readiness Requirements:**

a. Grantees must complete the following trainings:

- Basic fundamentals of HIV/AIDS training, as recognized by the State.
- State-certified HIV Counseling, Testing, and Reporting (CTR) Services
- Fundamentals of Rapid HIV Testing and Pre/Post Test Prevention Counseling with the OraQuick® Rapid HIV-1 Antibody Test *(provided by SAMHSA or CDC, and State training, as required).*

b. CLIA Certificate of Waiver: Trained grantees must obtain a Clinical Laboratory Improvement Amendments (CLIA) certificate of waiver. Instructions on how to obtain this waiver are available on CDC's website at: www.cms.gov/clia/cliaapp.asp

c. State regulations: Grantees must adhere to their State HIV testing regulatory requirements. Copy of State compliance documentation on rapid HIV testing (i.e., HIV Prevention Counseling, Partner Notification, Disease Reporting protocol) must be provided. State agency contacts are listed at www.cms.gov/clia/ssa-map.asp

d. Linkages to Care: Trained service providers must provide a signed Memoranda of Understanding or Agreement demonstrating established referral networks for clients needing appropriate counseling, treatment, and support services. Linkages to care must consist of, but are not limited to, partnership(s) with: local health departments and AIDS service organizations to secure appropriate HIV/AIDS support resources including laboratory services, HIV/AIDS primary and behavioral health care services, Hepatitis services, and other necessary support services (e.g., insurance, housing, food, transportation).

e. Rapid HIV Testing Quality Assurance Plan: Trained service providers must provide a copy of their site's rapid testing policies, procedures, and Quality Assurance (QA) plan (i.e., records management, self-monitoring protocol, test reliability and validity, and use of control kits). For information on CDC's QA guidelines, visit: http://www.cdc.gov/hiv/rapid_testing/materials/QA-Guide.htm.

f. **Policies & Procedures**: Grantee must provide a copy of the following policies and procedures before initiating SAMHSA's new rapid testing protocol:

- *Informed Consent form* – Grantee must have an informed consent form for clients to give consent to confidential or anonymous testing and HIV prevention and risk reduction counseling.
- *Legal/Ethical Policies* - Grantee must know their state laws regarding who may implement Counseling, Testing, and Referral (CTR) procedures and disclosure of an individual's HIV status (whether positive or negative) to partners and other parties. Organizations are also obligated to inform clients about state laws regarding the reporting of child abuse, sexual abuse of minors, and elder abuse.
- *HIPAA Compliance/Participant Protection and Confidentiality* – Grantee must maintain the confidentiality of client records according to the provisions of Title 42 of the Code of Federal Regulations, Part II. *For information on HIPAA compliance*, visit: www.hhs.gov/ocr/hipaa.
- *Safety* – Grantee must have guidelines for personal safety and security in non-traditional settings, for assuring minimal safety standards (including biohazard waste disposal) as outlined by the Occupational Safety and Health Administration.
- *Volunteers* – Grantee using volunteers must follow State requirements.
- *Data Security* - Grantee must collect and report data consistent with SAMHSA/CDC requirements to ensure data security and confidentiality. This includes written protocols on how to collect and analyze CTR data according to State and local policies.

5. **Monitor process, evaluate effectiveness, sustain effective programs/activities, and improve or replace those that fail:**
Grantees will be accountable for the results of their Minority SA/HIV/Hep SPF grant project. Grantees are, therefore, expected to play a critical role in providing on-going monitoring and evaluation of all the Minority SA/HIV/Hep SPF project activities. Through these efforts, the grantees will assess program effectiveness, ensure service delivery quality, identify successes, encourage needed improvement, and promote sustainability of effective policies, programs, and practices. Grantees will be expected to provide performance data to SAMHSA and the SPF State Incentive Grant Epi Workgroup (if available in their State) on a regular basis, as described in Section 2.3, Data and Performance Measurement, of this announcement. Grantees must be prepared to adjust their implementation plans based on the results of monitoring/evaluation activities.

In addition, grantees are encouraged to submit data and evaluation results when completed, to SAMHSA's National Registry of Effective Programs and Practices (NREPP) for review and rating as effective programs or practices.

2.2 INCLUSION OF REENTRY MINORITY POPULATIONS

Substance abusers are disproportionately involved in criminal activity. According to data from the National Institute of Justice's Arrestee Drug Abuse Monitoring (ADAM), about 66% of adult and more than 50% of juvenile arrestees tested positive for one or more illicit drugs in 1999.

Each year since 1999, approximately 600,000 inmates have been released back into communities, many of which are communities of color. An estimated 33% of these individuals have a substance abuse disorder, and other medical and mental health problems. Of particular concern is that many of these individuals upon their release are unaware of their HIV and hepatitis serostatus and engage in substance abuse and other high-risk behaviors, putting themselves and others at an even greater risk for HIV and hepatitis transmission. Those who are aware of their serostatus often have few connections in the community to help them access local SA, HIV, and/or hepatitis prevention, treatment and other supportive care services.

SAMHSA is committed to reducing the rates of SA, HIV/AIDS, and hepatitis among reentry populations. **Applicants are required to address the need for SA, HIV, and hepatitis prevention services for reentry minority populations as part of their grant project.**

2.3 DATA AND PERFORMANCE MEASUREMENT

1. The Government Performance and Results Act of 1993 (P.L.103-62, or "GPRA") requires all Federal agencies to:

   - Develop strategic plans that specify what they will accomplish over a 3- to 5-year period;
   - Set performance targets annually related to their strategic plan; and
   - Report annually on the degree to which the previous year's targets were met.

   The law further requires agencies to link their performance to their budgets. Agencies are expected to evaluate their programs regularly and to use results of these evaluations to explain their successes and failures.

   To meet these requirements, SAMHSA must collect performance data from grantees using GPRA and PARTS measures. Grantees are required to report these performance data to SAMHSA on a timely basis so that results are available to support budgetary decisions.

   Specifically, grantees will be required to provide data on a set of required measures based on the allowable activities in Section 2.1 of this announcement. The data collection tools to be used for reporting the required data will be provided in the application kits distributed by SAMHSA's clearinghouses and posted on SAMHSA's website. In your application, you must demonstrate your ability to collect and report on these measures, and you may be required to provide some baseline data. The terms and conditions of the grant award also will specify the data to be submitted and the

schedule for submission. Grantees will be required to adhere to these terms and conditions of award.

2. Grantees are required to collect and report on several key measures specific to the rapid HIV testing component of this initiative. SAMHSA may require data collection and reporting from the current HIV Counseling and Testing Report (CTR) Form. However, in the future, there may be additional data measures that grantees will be required to collect. Written assurances agreeing to provide such data, datasets, and written protocols on how to collect and analyze the HIV CTR data, must be submitted in **Appendix 2** of your application.

3. SAMHSA is currently finalizing National Outcome Measures specific to substance abuse prevention that are highly correlated at the local, State and national levels. When the measures are finalized, grantees will be required to collect and report on the SAMHSA's substance abuse prevention measures described in the following table.

National Outcomes		Substance Abuse Prevention Measures
I.	Abstinence from drug use/alcohol abuse	30-day substance use (non-use/reduction in use)-adult and youth
		Perceived risk of use-adult and youth
		Age of first use-adult and youth
		Perceived Disapproval of use-youth
II.	Increased/Retained Employment or Return to School	Consequences of ATOD use in workplace-adult; Suspensions and expulsions related to ATOD and/or violent behavior in school-youth
III.	Decreased Criminal Justice Involvement	ATOD Related Criminal behavior-adult and youth
IV.	Increased Stability in Family and Living Conditions	Family communication-adult and youth
V.	Increased Access to Services	Number of persons served by age, gender, race, and ethnicity
VI.	Increased Social Support/ Social Connectedness	Collective efficacy-adult Community involvement-adult and youth
VII.	Cost Effectiveness	Cost bands (TBD)
VIII.	Use of Evidence-Based Practices	Total number of Evidence-Based programs funded

4. In addition to the required performance data, grantees are required to identify and report the amount of funding supporting reentry minority populations each year of the project. Finally, grantees may choose to collect additional data to monitor progress in addressing site-specific needs identified in their community-wide needs assessment. Applicants should specify and justify any additional measures they plan to collect in their applications.

2.4 GRANTEE MEETINGS

Grantees must budget to send a minimum of two people (including the Project Director and Evaluator) to attend a 3-day mandatory grantee meeting each year of the project. Grantee meetings are usually held in the Washington, D.C. metropolitan area. At these meetings, grantees will present their projects, network with other grantees, and receive extensive technical assistance from federal staff and contractors.

2.5 EVALUATION

Grantees must conduct on-going monitoring and evaluation of their projects to assess program effectiveness. After award, grantees will be required to submit to the CSAP GPO or other designated entity, revisions to their data collection and evaluation plans based on the results of their needs assessment, on-going work of key stakeholders, and the development of the comprehensive strategic plan. Grantees must be prepared to adjust their implementation plans based on the GPO feedback to the project to improve services.

The evaluation must include both process and outcome components. Process and outcome evaluations must measure change related to project goals and objectives over time and compared with baseline data.

Process components should address issues such as:

- How closely did implementation match the plan?
- What types of deviation from the plan occurred?
- What led to the deviations?
- What effect did the deviations have on the planned intervention and evaluation?
- Who (program, staff) provided what services (modality, type, intensity, duration), to whom (individual characteristics), in what context (system, community), and at what cost (facilities, personnel, dollars)?

Outcome components should address issues such as:

- What program/contextual factors were associated with outcomes?
- What individual factors were associated with outcomes?
- How durable were the effects?

Although control groups are not required, communities must identify potential sources of comparison data at the local (i.e., tribal jurisdictions, county, towns) level. The evaluation plan must be accurately reflected in cost items as part of the overall budget.

No more than 20% of the total grant award may be used for evaluation and data collection and analysis, including GPRA.

In addition to conducting a site-specific evaluation, grantees must participate in a multi-site evaluation conducted by CSAP or under the guise of an authorized organization. This multi-site evaluation may include the use of common data collection instruments and routine data reporting procedures. Grantees must explicitly state their willingness to

participate in the multi-site evaluation in their applications, including their willingness to provide required forms, data and reports related to the multi-site evaluation.

II. AWARD INFORMATION

1. AWARD AMOUNT

It is expected that a total of $20.6 million will be available to fund 59-82 awards in fiscal year 2005. The average annual award will range from $250,000-$350,000 per year in total costs (direct and indirect). The maximum allowable award is $350,000 in total costs (direct and indirect) per year for up to 5 years. Proposed budgets cannot exceed the allowable amount in any year of the proposed project.

The actual amount available for the awards may vary, depending on unanticipated program requirements and the number and quality of the applications received. Annual continuation awards will depend on the availability of funds, grantee progress in meeting project goals and objectives, and timely submission of required data and reports.

2. FUNDING MECHANISM

Awards will be made as cooperative agreements.

Role of the Grantee

The Grantee must comply with the terms of the Minority SA/HIV/Hep SPF Initiative including implementation of all required SPF activities described in Section I.2, *Expectations*, in this grant announcement. The Grantee must agree to provide SAMHSA with all required performance data, collaborate with SAMHSA/CSAP staff in all aspects of the Minority SA/HIV/Hep SPF Initiative, and participate in the cross-site evaluation (including submission of all required forms, data and reports).

Role of Federal Staff

The design of this program necessitates participation of the Government Project Officer in two key aspects of the grant projects: 1) review and approval of the needs assessment (to ensure that the grant activities will be directed to those areas with the greatest need for substance abuse, HIV, and hepatitis prevention, and 2) review and approval of the strategic plan to ensure activities are targeted to the areas with greatest need, and that the identified evidence-based SA, HIV, and hepatitis practice or program is appropriate for the target population. The GPO also will provide on-going monitoring and technical assistance and coordinate the collection and data analysis of GPRA and other performance measurement requirements.

III. ELIGIBILITY INFORMATION

1. ELIGIBLE APPLICANTS

Eligible applicants are community-level domestic public and private nonprofit entities. For example, non-profit community-based organizations, faith-based organizations, colleges and universities, health care delivery organizations, local governments, tribal governments, tribal organizations and tribal urban Indian entities are eligible to apply. Since the purpose of

this RFA is to expand the capacity of community-level domestic public and private non-profit entities, State and national organizations are not eligible to apply.

Eligibility is limited to applicants from geographic areas with high AIDS case rates. Only applicants located in, or in close proximity to and proposing to provide services in, one of the following are eligible to apply:

a) Geographic areas within States with an annual AIDS case rate of at least 10 cases per 100,000 people.

b) Metropolitan Statistical Areas (MSAs) with an annual AIDS case rate of at least 20 cases per 100,000 people among minority populations.

See Appendix B of this document for States and MSAs that meet the above criteria based on data from the Centers for Disease Control and Prevention (CDC). Only applicants serving geographic areas within States and MSAs listed in Appendix B can apply. Applicants must specify in Appendix 6 of their applications the MSA or geographic area within a State where services are proposed.

SAMHSA is limiting eligibility to applicants serving MSAs and States listed in Appendix B because, in the absence of consistent data reporting by all jurisdictions, the best indicator of the magnitude of the epidemic is AIDS case rates derived from the CDC HIV/AIDS surveillance reports.

2. COST SHARING

Cost sharing is not required in this program, and applications will not be screened out on the basis of cost sharing. However, you may include cash or in-kind contributions in your proposal as evidence of commitment to the proposed project. Reviewers may consider this information in evaluating the quality of the application.

3. OTHER

3.1 Additional Eligibility Requirements

Applications must comply with the following requirements, or they will be screened out and will not be reviewed: use of the PHS 5161-1 application; application submission requirements in Section IV-3 of this document; and formatting requirements provided in Section IV-2.3 of this document.

3.2 Evidence of Experience and Credentials

SAMHSA believes that only existing, experienced, and appropriately credentialed organizations with demonstrated infrastructure and expertise will be able to provide required services quickly and effectively. Therefore, in addition to the basic eligibility requirements specified in this announcement, applicants must meet three additional requirements related to the provision of services.

The three requirements are:

- A provider organization for direct substance abuse prevention services appropriate to the grant must be involved in each application. The provider may be the applicant or another organization committed to the project. More than one provider organization may be involved;

- Each direct service provider organization must have at least 2 years experience providing services in the geographic area(s) covered by the application, as of the due date of the application; and

- Each direct service provider organization must comply with all applicable local (i.e., town, city, county) and State/tribal licensing, accreditation, certification requirements as of the due date of the application. [Note: SAMHSA/CSAP understand that prevention service providers generally are not subject to licensing, accreditation or certification requirements. However, other service provider organizations participating in the project, such as health care providers and/or substance abuse treatment providers, may be subject to licensure, accreditation and/or certification requirements.]

  [Note: The above requirements apply to all service provider organizations. A license from an individual clinician will not be accepted in lieu of a provider organization's license.]

In **Appendix 7** of the application, you must: (1) identify at least one provider of direct substance abuse prevention services, (2) include a list of all direct service provider organizations that have agreed to participate in the proposed project, including type of services each provides; and (3) include the Statement of Assurance (provided in Appendix D of this announcement), signed by the authorized representative of the applicant organization identified on the face-page of the application, that all participating service provider organizations:

- Meet the 2-year experience requirement,
- Meet applicable licensing, accreditation, certification requirements, and,
- If the application is within the funding range, will provide the Government Project Officer (GPO) with the required documentation within the time specified.

In addition, if, following application review, an application's score is within the fundable range for a grant award, the GPO will call the applicant and request that the following documentation be sent by overnight mail:

- A letter of commitment that specifies the nature of the participation and what service(s) will be provided from every service provider organization that has agreed to participate in the project;

- Official documentation that all participating organizations have been providing relevant services for a minimum of 2 years before the date of the application in the area(s) in which the services are to be provided; and

DPS PROJECT CHECKLIST

For DPS Use Only
Date Received
Date Returned
Date Accepted
CA/CN's Name

IMPORTANT: PLEASE READ AND FOLLOW THE INSTRUCTIONS FOR COMPLETING THE PROJECT CHECKLIST AND CONTACT THE APPROPRIATE UNIT MANAGER IF YOU HAVE ANY FURTHER QUESTIONS. ALL INFORMATION SHOULD BE COMPLETED, ATTACH ALL REQUIRED MATERIALS AND SUBMIT FOR HANDLING TO THE DEPARTMENT OF PROCUREMENT SERVICES, ROOM 403, CITY HALL, 121 N. LASALLE STREET, CHICAGO, ILLINOIS 60602.

GENERAL INFORMATION:

Date: 7/17/09
REQ No.: 44238

Contact Person: Maribel Valdez
Tel: 7-8828 **Fax:** 7-9398 **E-mail:** @cityofchicago.org

Specification No.: (if known): 44238
PO No.: (if known): 11616

Project Manager: Cathy Yanda
Tel: 7-9656 **Fax:** 7-9398 **E-mail:** @cityofchicago.org

Modification No.: (if known):1
Previous PO No.: (if known):

Project Description: PURCHASE OF ORAQUICK ADVANCE RAPID HIV-1/2 ANTIBODY TEST KITS AND CONTROLS

FUNDING:

City:	☒ Corporate	☐ Bond	☐ Enterprise	☐ Grant*	☐ Other
State:	☐ IDOT/Transit	☐ IDOT/Highway		☐ Grant*	☐ Other
Federal :	☐ FHWA	☐ FTA	☐ FAA	☐ Grant*	☐ Other

LINE	FY	FUND	DEPT	ORGN	APPR	ACTV	OBJT	PROJECT	RPTG	$ DOLLAR AMOUNT
001	009	0100	0413350	9129	220342					900000

Estimated Value $900,000

*IF GRANT FUNDED, A COPY OF THE APPROVED GRANT AND APPLICATION ARE REQUIRED and any other Terms and Conditions that may apply.

SCOPE STATEMENT:

☒ Attached is a Detailed Scope of Services and/or Specification

IMPORTANT: THIS IS A CRITICAL PORTION OF YOUR SUBMITTAL. IN ORDER FOR DPS TO ACCEPT YOUR SUBMITTALYOU MUST COMPLETE THE SPECIFIC SCOPE REQUIREMENTS AS SET FORTH IN THE SUPPLEMENTAL CHECKLIST FOR THAT UNIT.

The following is a general description of what should be included in a Scope of Services or Specification:
A clear description of all anticipated services and products, including: time frame for completion, special qualifications of prospective vendors, special requirements or needs of the project, locations, anticipated participating user departments, citation of any applicable City ordinance or state/federal regulation or statute.

TYPE OF PROCUREMENT REQUESTED (check all that apply):

NEW REQUEST
- ☐ Blanket Agreement
- ☐ Standard Agreement
- ☐ Small Orders

MOD/AMENDMENT
- ☒ Time Extension
- ☒ Vendor Limit Increase
- ☐ Scope Change/Price Increase/Additional Line Item(s)
- ☐ Other (specify):

FORMS: ☒ Requisition ☐ Special Approvals ☐ Non-Competitive Review Board (NCRB)

CONTRACT TERM: 3YRS **Requested Term (number of months):** 1/1/10 12/31/13

PRE BID/SUBMITTAL REQUIREMENTS:

Requesting Pre Bid/Submittal Conference? ☐ Yes ☒ No Requesting Site Visit? ☐ Yes ☒ No

DPS PROJECT CHECKLIST

ARCHITECTURAL/ENGINEERING SUPPLEMENTAL CHECKLIST

Required Attachments: Scope of Services, including location, description of project, services required, deliverables, and other information as required

Risk Management

Will services be performed within 50 feet of CTA train or other railroad property? ☐Yes ☐No

Will services be performed on or near a waterway? ☐Yes ☐No

If applicable, Pre-Qualification Category No. Category Description:

For Pre-Qualification Program, attach list of suggested firms to be solicited

Other Agency Concurrence Required: ☐None ☐State ☐ Federal ☐ Other (fill in)

AVIATION CONSTRUCTION SUPPLEMENTAL CHECKLIST

DOA sign-off for final design documents: ☐Yes ☐ No

Required Attachments:

Copy of Draft Contract Documents and Detailed Specifications.

Risk Management:

Current Insurance Requirements prepared/approved by Risk Management: Yes ☐ No ☐

Will work be performed within 50 feet of CTA or ATS structure or property? Yes ☐ No ☐

Will work be performed airside? Yes ☐ No ☐

***NOTE:** Any non-construction Aviation request, complete the applicable section.

COMMODITIES SUPPLEMENTAL CHECKLIST

Required Attachments: Detailed Specifications (Scope of Services) including detailed description of the product, delivery location, user department contact, price escalation considerations, Bidder's qualification, contract term and extension options, Contractor's qualifications, citation of any applicable City/State/Federal statutes or regulations, citation of any applicable technical standards and Price Lists/Catalogs, technical drawings and other exhibits and attachments as appropriate.

If Modification request, please verify and provide the following:

Contractor's Name:	OraSure Technologies, Inc.
Contractor's Address:	220 East First Stree
	Bethlehem, PennSylvania, 18015-1360
Contractor's e-mail Address:	www.orasure.com
Contractor's Phone Number:	610-882-1820
Contractor's Contact Person:	610-882-1825

CONSTRUCTION SUPPLEMENTAL CHECKLIST

Required attachments:

Copy of Draft (80% Completion), Contract Documents and Detailed Specifications

Risk Management

Will services be performed within 50 feet of CTA train or other railroad property? ☐ Yes ☐ No

Will services be performed on or near a waterway? ☐ Yes ☐ No

CITY OF CHICAGO
PURCHASE REQUISITION

Copy (Department)

DELIVER TO:	REQUISITION: 44238
041-3350 HIV/AIDS/STD ACTIVITY OFFICE 50 W WASHINGTON Chicago, IL 60601	PAGE: 1 DEPARTMENT: 41 - DEPARTMENT OF HEALTH PREPARER: Maribel E Valdez NEEDED: APPROVED: 7/16/2009

REQUISITION DESCRIPTION

PURCHASE OF ORAQUICK ADVANCE RAPID HIV-1/2 ANTIBODY TEST KITS AND CONTROLS
SPECIFICATION NUMBER: 11616

COMMODITY INFORMATION

LINE	ITEM	QUANTITY	UOM	UNIT COST	TOTAL COST
1	19340	1,095.00	Day	0.00	**0.00**
	EXTENSION OF CONTRACT FOR 3 YEARS				

SUGGESTED VENDOR: ORASURE TECHNOLOGIES INC **REQUESTED BY:** Maribel E Valdez

DIST	BFY	FUND	COST CTR	APPR	ACCNT	ACTV	PROJECT	RPT CAT	GENRL	FUTR	Dist. Amt.
1	009	0100	0413350	9129	220342	0000	00000000	000000	00000	0000	0.00

LINE TOTAL: **0.00**

LINE	ITEM	QUANTITY	UOM	UNIT COST	TOTAL COST
2	19340	900,000.00	USD	0.00	**0.00**
	VENDOR LIMIT INCREASE FOR 3 YEAR EXTENSION				

SUGGESTED VENDOR: **REQUESTED BY:** Maribel E Valdez

DIST	BFY	FUND	COST CTR	APPR	ACCNT	ACTV	PROJECT	RPT CAT	GENRL	FUTR	Dist. Amt.
1	009	0100	0413350	9129	220342	0000	00000000	000000	00000	0000	0.00

LINE TOTAL: **0.00**

REQUISITION TOTAL: **0.00**

Where a commodity is for a particular or unique use other than standard quality, grades, color, size or other characteristics, give details of how it will be and for what purpose.
Requisitions prepared incorrectly will be returned to the using department.

City of Chicago
Richard M. Daley, Mayor

Department of Public Health

Terry Mason, M.D., F.A.C.S.
Commissioner

333 South State Street
Chicago, Illinois 60604
(312) 747-9884
(312) 747-9888 (24 hours)

http://www.cityofchicago.org/health

MEMORANDUM

Date: July 16, 2009

To: Montel M. Gayles
Chief Procurement Officer

Attn: Elvia Fernandez
Director of Procurement Services

From: Terry Mason, M.D., F.A.C.S.
Commissioner

Subject: Justification for Vendor Limit Increase and extension

Re: OraSure Technologies, Inc.; $900,000; Specification No. 40826; PO No. 11616.

The Chicago Department of Public Health (CDPH) is requesting a vendor's limit increase to the above referenced contract.

The increase is required for the CDPH HIV/AIDS Program (the Division) for the purchase of the OraQuick Advance Rapid HIV-1/2 antibody test kits and controls provided by OraSure Technologies, Inc. Testing for HIV is a critical part of the mission of the Department and the Division.

The estimated amount of $900,000 for the vendor limit increase is required to cover the purchase of the testing kits for the three year extension of the contract extended from January 1, 2010 through December 31, 2013.

Thank you for your assistance in this matter. If you have any questions or need additional information, please contact Maribel Valdez at 312-747-8828.

cc: Elvia Fernandez
Kathy Yanda
File

PO 11616

The Chief Procurement Officer has determined that the nature of the services to be provided under this contract is such that neither direct nor indirect subcontracting opportunities will be practicable or cost effective. Therefore, there will be no stated goals for MBE/WBE participation resulting from this contract. This determination is being made pursuant to Section 2-92-450 of the Municipal Code of Chicago.

3.15. CONTRACT DOCUMENTS TO BE COMPLETED BY CONTRACTOR

The Contractor must fully complete, sign, notarize and submit as part of your proposal the following documents incorporated herein:

1. Economic Disclosure Statement and Affidavit
2. Proposal Execution Page, as applicable (Corporation, Partnership, Sole Proprietorship).
3. City of Chicago Insurance Certificate of Coverage

3.16. CONTRACT PERIOD

The contract will begin on or about January 1, 2007 and continue through December 31, 2009, unless terminated prior to this date according to the terms of the Termination paragraph, or extended as provided for herein.

3.17. CONTRACT EXTENSION OPTION

This Contract will be in effect for the dates indicated herein for the initial thirty-six (36) months contract period. The Chief Procurement Officer may exercise the City's unilateral right to extend this Contract following the expiration of the base contract term for up to three (3) years, subject to acceptable performance by the Contractor and contingent upon the appropriation of sufficient funds for the procurement of services provided for in this Contract.

No less than ninety (90) calendar days before the expiration of the then current contract term, the Chief Procurement Officer will give the Contractor notice of the City's intent to exercise its option to renew the Contract for the approaching option period. The date on which the Chief Procurement Officer gives notice is the date the notice is mailed, if it is mailed, or the date the notice is delivered, if sent by courier or messenger service.

With the same amount of notice as for options, the City reserves the right to extend the contract period for a period of no more than one hundred eighty-one (181) calendar days, either in lieu of exercising an option period or following the exhaustion of all option periods, for the purpose of providing continuity of service while procuring a replacement contract.

3.18. ACCEPTANCE

It is understood and agreed by and between the parties hereto, that the initial acceptance and inspection of any delivery will not be considered a waiver of any provision of these specifications and will not relieve the Contractor of its obligation to provide satisfactory OraQuick Advance Rapid HIV – ½ Antibody Test Kits which conforms to the specifications, as shown by any test or inspections for which provisions are herein otherwise made.

3.19. MODIFICATIONS/AMENDMENTS

No changes, amendments, modifications, cancellations or discharges of this Contract, or any part hereof, will be valid unless stipulated in writing and signed by the parties hereto, or their respective agents representatives.

Such changes which are mutually agreed upon by and between the City and the Contractor will be incorporated in written modifications to this contract.

CITY OF CHICAGO
DEPARTMENT OF PROCUREMENT SERVICES
ROOM 403, CITY HALL, 121 N. LA SALLE ST.

JNCP Form Rev ____

JUSTIFICATION FOR NON-COMPETITIVE PROCUREMENT

COMPLETE THIS SECTION IF NEW CONTRACT

For contract(s) in this request, answer applicable questions in each of the 4 major subject areas below in accordance with the Instructions for Preparation of Non-Competitive Procurement Form on the reverse side.

Request that negotiations be conducted only with OraSure Technologies Incorporated for the product and/or services described herein.
(Name of Person or Firm)

This is a request for ___ (One-Time Contractor Requisition # 23802, copy attached) or _XXX_ Term Agreement or Delegate Agency _____ (Check one). If Delegate Agency, this request is for "blanket approval" of all contracts within the _____ (Attach List)
Pre-Assigned Specification No. (Program Name) _____
Pre-Assigned Contract No. _____

COMPLETE THIS SECTION IF AMENDMENT OR MODIFICATION TO CONTRACT

Describe in detail the change in terms of dollars, time period, scope of services, etc., its relationship to the original contract and the specific reasons for the change. Indicate both the original and the adjusted contract amount and/or expiration date with this change, as applicable. Attach copy of all supporting documents. Request approval for a contract amendment or modification to the following:

Contract #: _____ Company or Agency Name: _____

Specification #: _____ Contract or Program Description: _____
Mod. #: _____ (Attach List, if multiple)

Paul LaKosky	747-9655		Health	09/08/05
Originator Name	Telephone	Signature	Department	Date

Indicate SEE ATTACHED in each box below if additional space needed:

( ) **PROCUREMENT HISTORY**
The City of Chicago has had a term agreement with OraSure Technologies since 2002. This supply requirement cannot be competitively bid as OraSure Technologies, Inc. ("OraSure") is the only licensed manufacturer and sole distributor of the OraQuick® Advance Rapid HIV – 1/2 Antibody Test, OraSure oral fluid HIV-1 anti-body collector device, and the OraQuick® Advance Rapid HIV – 1/2 Controls.

( ) **ESTIMATED COST**
$300,000 per year for 3-years Total Estimated Cost $900,000

( ) **SCHEDULE REQUIREMENTS**

See attached price quotes

( ) **EXCLUSIVE OR UNIQUE CAPABILITY**
OraSure Technologies, Inc. ("OraSure") is the only licensed manufacturer and sole distributor of the OraQuick® Advance Rapid HIV – 1/2 Antibody Test, OraSure oral fluid HIV-1 anti-body collector device, and the OraQuick® Advance Rapid HIV – 1/2 Controls.

( ) **OTHER**

APPROVED BY: _____ 10/3/05 _____ _____
DEPARTMENT HEAD OR DESIGNEE — DATE — BOARD CHAIRPERSON — DATE

Sole Source Justification: OraSure Technologies Incorporated

In June 2003 the Chicago Department of Public Health, Division of STD/HIV/AIDS Public Policy and Programs received an award from the Centers for Disease Control and Prevention (CDC) in Atlanta, GA under the Post-Market Surveillance for OraQuick™ Rapid HIV-1 Testing Initiative. The purpose of this initiative was to conduct multi-site pilot studies to assess the feasibility and acceptability of OraSure Technologies 1st generation OraQuick rapid HIV-1 testing – a blood/whole serum-based test and at the time a new testing technology- in non-clinical settings (e.g., jails, public parks, universities, community-based organizations, etc.). CDPH partnered with 5 community-based organizations to integrate OraQuick testing into their organizations as well as introducing OraQuick into all CDPH clinics and the Sheriff's Female Furlough Program.

During Chicago's pilot study approximately 950 individuals were tested using the device. Of those tested approximately 1.9% (18) were found to be HIV positive. This represents a 1% increase is the HIV seropositivity rates over individuals tested using conventional HIV-1 testing methods. Many of the individuals tested stated that they would not have tested for HIV if the OraQuick rapid HIV-1 test had not been available as a testing option. This project was renewed in January 2004 - and extended through FY 2006- due to its continued success. Lastly, during 2005 CDPH was awarded a 5-year grant from the Substance Abuse and Mental Health Services Administration (SAMHSA) program announcement CFDA No. 93.243): Substance Abuse, HIV, and Hepatitis Prevention for Minority Populations in Communities of Color. Rapid HIV-1/2 Testing is an integral component of this program which will run through 2010.

In September 2003 the Chicago Department of Public Health, Division of STD/HIV/AIDS Public Policy and Programs received an additional award for Rapid Testing under CDC program announcement 2003-N-00894: Project 3 - Using HIV Rapid Testing to Improve Outcomes of Partner Counseling and Referral Services. This award was initially to cover the period 09-14-03 through 09-14-05, but was extended through 06-14-2006.

In November 2004 OraSure Technologies was granted FDA approval of their 2nd generation rapid HIV-1/2 test marketed under the name OraQuick Advance.™ This device is capable of detecting HIV – 1 or 2 antibodies in oral mucosal transudate (i.e., cells found in the mouth). Using this technology CDPH has conducted or facilitated the testing of 700 high-risk individuals each month in non-traditional/non-clinical settings.

OraSure Technologies, Inc. ("OraSure") continues to be the only licensed manufacturer and sole distributor of the OraQuick Advance Rapid HIV – 1/2 Antibody Test, OraSure oral fluid HIV-1 anti-body collector device, and the OraQuick® Advance Rapid HIV – 1/2 Controls.

Specification:

OraSure HIV – 1 Oral Fluid Testing Device

The OraSure® HIV-1 Oral Specimen Collection Device is an oral fluid collection device that detects the presence of HIV – 1 in human oral fluid. A collection pad is placed between the lower cheek and gum for 2 to 5 minutes. OraSure® is designed to draw out HIV-1 antibodies, not the virus, from the tissues of the cheek and gum. OraSure® HIV-1 does not collect saliva but rather a sample called oral mucosal transudate (OMT).

OraSure® HIV-1 offers healthcare professionals an HIV-1 testing option without the risk of needle stick accidents and gives patients accurate results without having to give blood

OraQuick® Advance™ Rapid HIV – 1/2 Testing Kits

OraQuick® **Advance™** is an FDA approved rapid point-of-care fingerstick and venipuncture whole blood test used to aid in the diagnosis of HIV-1 infection. This Clinical Laboratory Improvements Amendments of 1988 (CLIA) waived test, which detects the presence of antibodies to HIV-1, requires only a drop of blood and can produce results in 20 minutes.

Based on the results from a large controlled clinical trial, the overall sensitivity and specificity of the OraQuick® Advance™ Rapid HIV-1 Antibody test was shown to be 99.6% and 100.0% respectively, using fingerstick and venipuncture whole blood specimens.

OraQuick® Advance™ HIV-1/2 offers healthcare professionals an HIV-1/2 testing option without the risk of needle stick accidents and gives patients accurate results without having to give blood

OraQuick® Advance™ Rapid HIV – 1/2 Controls

OraQuick® Advance™ Kit controls are human plasma-based reagents. The Kit Controls are specially formulated and manufactured to ensure performance of the Test, and are used to verify the ability of the counselor to properly perform and interpret the results. The HIV – 1 and HIV – 2 Positive Controls will produce a reactive test result and have been manufactured to produce a very faint result. The Negative Control will produce a non-reactive test result.

These supplies will be shipped to the following CDPH clinics in care of the following individuals.

CDPH Lakeview Specialty Clinic
ATTN: Rick Ortiz, Rapid Testing Coordinator
2861 N. Clark Street
Chicago, IL 60657 Phone: 312.744.5507

CDPH 31st Specialty Clinic
ATTN: Yvette Winston, Director of Administrative Services I
530 E. 31st St.
Chicago, IL 60616 Phone: 312.747.5409

Estimated Cost:

OraSure HIV – 1 Oral Fluid Testing Device

24,340 – 16, 949 OraSure HIV – 1 Oral Fluid Testing Devices @ $4.10 - $5.90ea = **$100,000**

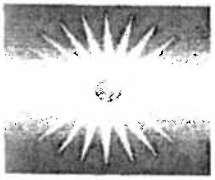
OraQuick Advance Rapid HIV – 1/2 Testing Kits

10,000 OraQuick Advance Rapid HIV – 1/2 Testing Kits @ $18.00ea = **$180,000**

OraQuick Advance Rapid HIV – 1/2 Controls

800 OraQuick Advance Rapid HIV – 1/2 Controls @ $25.00ea = **20,000**

Total Estimated Cost: **$300,000**



OraSure Technologies, Inc.

diagnostic solutions for the new millennium

September 8, 2005

Mr. Paul Lakosky
Chicago Dept. of Public Health
31st Street, Specialty Clinic
530 E. 31st Street
Chicago, IL 60616

SUBJECT: Sole Source Letter for OraQuick ADVANCE

Dear Mr. Lakosky:

OraSure Technologies, Inc. ("OraSure") is the only licensed manufacturer of the OraQuick® ADVANCE Rapid HIV-1/2 Antibody Test (the "OraQuick® Test"), PMA# BP010047, product numbers 1001-0079,1001-0078 and OraQuick® ADVANCE Rapid HIV-1 / 2 Control, P/N 1001-0077. OraSure is also the sole source for obtaining this OraQuick® Test and controls.

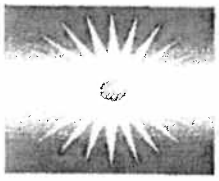
Thank you for your continued support of OraSure Technologies. If you need any further information, please contact me at 916-782-3119 or e-mail: preis@orasure.com.

Sincerely,

Patricia Reis

Patricia Reis
Contracts Administrator

220 East First Street • Bethlehem, Pennsylvania 18015-1360
Phone 610-882-1820 • Fax 610-882-1825
www.orasure.com



OraSure Technologies, Inc.

diagnostic solutions for the new millennium

September 7, 2005

Mr. Paul Lakosky
Chicago Dept. of Public Health
31st Street, Specialty Clinic
530 E. 31st Street
Chicago, IL 60616

SUBJECT: Quote for OraSure® HIV-1 Oral Fluid Devices, P/N 503-0050

Dear Mr. Lakosky:

OraSure Technologies, Inc. (OTI) is pleased to provide the below listed price quote for OraSure® HIV-1 Oral Fluid devices per your request.

OraSureTechnologies, Inc. is the manufacturer and sole provider of the FDA approved OraSure, oral fluid HIV-1 antibody collector device; PMA BP910001, P/N 503-0050 product as listed below. Furthermore, these collectors cannot be obtained through any distribution network in the United States and must be purchased directly from OraSure Technologies, Inc.

Item #	Description	Unit Price	Qty
503-0050	**OraSure®** HIV-1 Oral Fluid Devices, 50 ct	$295.00	Less than 20 cases per order
503-0050	**OraSure®** HIV-1 Oral Fluid Devices, 50 ct	$205.00	20+ cases per order

FOB point is Bethlehem, PA. Freight charges will be prepaid and added to your invoice. Payment terms are Net 30 days from invoice date. Delivery will be 14 - 21 days ARO. OraSure's Federal ID# is 36-4370966.

Payment Address:
OraSure Technologies, Inc.
Dept. 269701
PO Box 67000
Detroit, Michigan 48267-2697

Customer Service
To place orders please call 800-869-3538 or 610-882-1820 or Fax Orders to 610-882-3572. Emails may be sent to customerservice@orasure.com. Office Hours are 8 a.m. to 6 p.m. (Eastern Time).

Should you require additional information, please contact me at 916-782-3119.

Regards,
Patricia Reis
Patricia Reis
Contract Manager

PAGE 1 OF 1

CITY OF CHICAGO ALL PURPOSE REQUISITION FORM

DEPT USE 1	DEPT USE 2

DATE	BUREAU/DIVISION	SHIP CODE	SHIP TO: ATTN.:	DATE NEEDED	PO/RX NUMBER	PV NUMBER

LINE TERM	LINE FUND	COMMODITY CODE	SYS CODE	DESCRIBE AND JUSTIFY GOODS OR SERVICES, OR ENTER CATALOG INFORMATION — ITEM DESCRIPTION	CATALOG NAME/#	CATALOG DATE	CATALOG PAGE	CATALOG ITEM/PART #	UNIT PRICE	UNIT OF MEASURE	QUANTITY ORDER	QUANTITY RCV'D	TOTAL PRICE
	100								$1.50	case	16,000		
				1001 0077									
	100	43524418							$1.00	case	10,000		
				1001 0073									
	100	43524418							$2.00	pack	300		
				1001 0177									

COMMENTS:

CHECK OR COMPLETE ALL THAT APPLY	
PARTICIPATING TA #	
NEW TA OR CONTRACT: X	SOLE SOURCE
PURCHASE ORDER	CONTRACT AMENDMENT
DIRECT VOUCHER	EMERGENCY REQUEST
7-DAY BID	REJECTED

FY	LINE	FUND	DEPT	ORGN	APPR	ACTV	OBJT	PROJECT	RPTG	DOLLAR AMT.
06	1	100	41	3300	9129	0342				

PAGE TOTAL →

GRAND TOTAL (ALL PAGES) → $300,000

FOR FINANCE OFFICE USE ONLY	
CONTRACTS REVIEW — DATE	FINANCE DIRECTOR — DATE
EPS PASS 1 — DATE	EPS PASS 2 — DATE

VENDOR INFORMATION

COMPANY NAME Grainger

ADDRESS 220 E. First Street
Bethlehem, PA
18015-1360

VENDOR CODE

REP/PHONE

INVOICE NUMBER(S)

BUREAU/DIVISION INFORMATION

SECTION MANAGER/ APRF PREPARED BY

ADDRESS

DATE 1/4/15 PHONE 747 [illegible]

DEPUTY AUTHORIZATION

DATE PHONE

WHITE COPY – ORIGINAL YELLOW COPY – BUREAU/DIVISION PINK COPY – FINANCE DIVISION GOLD COPY – FILE

GRC-160847-34-2