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, Inc. for the product and/or services described herein.

This is a request for ____ (One-Time Contractor Requisition # __________, copy attached) or ____ XX ____ 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. ________ (Attach List) Pre-Assigned Contract No. ________

(Attach List) Pre-Assigned Specification No. ________ (Attach List) 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 #: 2308 Company or Agency Name: Chicago Department Of Public Health
Specification #: 11577
Mod.: __________ Contract or Program Description: Term Agreement for OraSure

Originator Name 312-747-9655 Signature
Telephone

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

( X ) PROCUREMENT HISTORY
The Chicago Department of Public Health STD/HIV Prevention & Care Program provides HIV Counseling & Testing citywide. Yearly, the Department test over 10,000 persons using the latest technology (OraSure Devices). The program is requesting to establish this contract to assist the program in its testing efforts for HIV disease

( X ) ESTIMATED COST
$58,200.00

( X ) SCHEDULE REQUIREMENTS
See attachment

( X ) EXCLUSIVE OR UNIQUE CAPABILITY
OraSure Technologies, Inc. is a sole source for devices

( ) OTHER

APPROVED BY: Wilhelm DEPARTMENT HEAD DATE 6-11-04
OR DESIGNEE

BOARD CHAIRPERSON DATE
JUSTIFICATION FOR NON-COMPETITIVE PROCUREMENT

COMPLETE THIS SECTION IF NEW CONTRACT(S)

For contract(s) in this request, answer applicable questions in each of the 4 major subjects 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, Inc. (Name of Person or Firm) for the product and/or services described herein.

This is a request for: ______ (One-Time Contract per Requisition #_______ copy attached) or ______ 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.
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: Chicago Department of Public Health STD/HIVP
Specification # ____________ Contract or Program Description: Term Agreement for OraSure
Mod # ____________ (Attach List, if multiple)

JANICE JOHNSON ____________ Telephone ____________ HEALTH ____________ 5/10/02
Original Name ____________ Signature ____________ Department ____________ Date

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

() PROCUREMENT HISTORY
Chicago Department of Public Health STD/HIV Prevention & Care Program provides HIV Counseling & Testing citywide. Yearly, we test over 10,000 persons using the latest technology (OraSure Devices). The program is requesting to establish a two-year contract to assist the program in its testing efforts for HIV disease.

() ESTIMATED COST
$10,780

() SCHEDULED REQUIREMENTS
See Attachment

() EXCLUSIVE OR UNIQUE CAPABILITY
OraSure Technologies, Inc. is a sole source for devices.

( ) OTHER

APPROVED BY ____________ 5/10/02 ____________ Board Chairperson ____________ Date
Department Head Or Designer ____________ Date
CITY OF CHICAGO
BLANKET PURCHASE ORDER

Furnish the supplies and/or services described below in conformance with conditions set forth herein and in your offer.

<table>
<thead>
<tr>
<th>DATE OF AWARD</th>
<th>DPT #</th>
<th>PURCHASE ORDER</th>
<th>SPECIFICATION NUMBER</th>
<th>VENDOR NUMBER</th>
<th>SITE NAME</th>
<th>DELIVERY DATE</th>
<th>PO START DATE</th>
<th>PO END DATE</th>
<th>PAGE #</th>
</tr>
</thead>
<tbody>
<tr>
<td>01/13/2004</td>
<td>2308</td>
<td>11577</td>
<td>1071875</td>
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<td></td>
<td>01/01/2003</td>
<td>12/31/2004</td>
<td>1</td>
<td></td>
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</tbody>
</table>

BUYER:
6400 ODELL BROWN 312-744-9806

ORDERED FROM:
ORASURE TECHNOLOGIES INC
P.O. BOX 67000
DEPT #269701
DETROIT, MI 482672697

PO DESCRIPTION: HIV ORAL SPECIMEN COLLECTION DEVICES

COMMODITY INFORMATION

<table>
<thead>
<tr>
<th>Line</th>
<th>Item</th>
<th>Item Description</th>
<th>UOM</th>
<th>Unit Cost</th>
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</thead>
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<tr>
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<td>4952610010</td>
<td>HIV-1 ORAL SPECIMEN - COLLECTION DEVICE, ORASURE NO. 503-0050</td>
<td>Case</td>
<td>192.50</td>
</tr>
</tbody>
</table>

Payment on this order will be made upon receipt of an original vendor invoice form referencing this order.

Mark all packages and papers with the purchase number.

Any deliveries containing overshipments will be reflected unless otherwise authorized in this purchase.

This purchase is subject to the City of Chicago General Conditions for Supplies. Work, or Professional Consulting Services; Special Conditions, Disclosure, Ownership, Acceptance Page, as applicable, which are attached hereto or incorporated herein by reference.
<table>
<thead>
<tr>
<th>Code Items</th>
<th>Description</th>
</tr>
</thead>
<tbody>
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<td>1935244100</td>
<td>HUMAN IMMUNODEFICIENCY VIRUS TYPE I &amp; II KITS - RAPID HIV-1, ORAQUICK 1001-0052, 25 CT</td>
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<td>1935244110</td>
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<tr>
<td>1935244120</td>
<td>HUMAN IMMUNODEFICIENCY VIRUS TYPE I &amp; II KITS - RAPID HIV CONTROL, ORAQUICK 1001-0049</td>
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<tr>
<td>1935244125</td>
<td>HUMAN IMMUNODEFICIENCY VIRUS TYPE I &amp; II KITS - RAPID HIV CONTROL, ORAQUICK 1001-0049</td>
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<tr>
<td>1935244300</td>
<td>HUMAN IMMUNODEFICIENCY VIRUS TYPE I &amp; II KITS - 100 TESTS/KIT</td>
</tr>
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</table>
Inter-Office Memorandum

To: Linda Parks
From: Monica Cardenas
Date: June 27, 2002
Re: Justification for Non-Competitive Procurement – OraSure Technologies, Inc.

On June 13, 2002 the members of the NCPRB reviewed your justification that negotiations be conducted with OraSure Technologies, Inc. for the purchase of the HIV Oral Specimen Collection Device. After hearing Ms. Magee’s presentation and reviewing the documents that were provided, the board members are requesting that the following items be addressed in order for a decision to be made:

1. You identified that OraSure Technologies, Inc. is the only licensed manufacturer and distributor of the OraSure HIV-1 Oral Specimen Collection Device. Is this the only oral specimen collection device on the market? If not, which other manufacturer(s) provide this type of product at the same level of testing. (Attach samples and/or literature of the product(s)).

2. The quote from the vendor is $10,780.00 for 56 cases at $192.50 per case. How many times a year do you anticipate ordering this product?

3. The price quote is for a two-year period from 05/01/02 – 04/30/04. If you anticipate ordering supplies more than once than the quote should reflect $10,780.00 times the number of orders you anticipate. For example $10,780.00 x 2 (112 cases per year) x 2 years = $43,120.00.

Thank you for your cooperation.

S. S. R. B.
DATE: July 11, 2002
APPROVED: 4-0
CONDITIONALLY APPROVED: 
RETURN TO DEPT: 
DISAPPROVED: 

[Signature]
7/11/02
Hi Monica I added the requested information. Also, a quote should come to you via fax within the next few minutes.

Janice

> -----Original Message-----
> From: Johnson, Janice
> Sent: Thursday, July 11, 2002 10:48 AM
> To: 'MCardenas@cityofchicago.org'
> Subject: OraSure HIV-1 Antibody Test

Hello Monica,

As per your request, the OraSure HIV-1 Oral Specimen Collection device is intended for the use in the collection of oral fluid specimens for the purpose of testing for the presence of HIV-1 antibodies. This device was FDA approved in 1994. Thus far, OraSure Technologies, Inc, in Bethlehem, Pennsylvania is the sole makers of this product. Our representative from the company is a Mr. Randy Ward, Account Manager, Public Health-Mid-West, 1800-869-3538x3264

OraTechnologies has developed another device called "Quick Test" which is due to hit the market within a couple of months. The big difference with this product is that results are given within 20 minutes as opposed to the 7 day wait time with the current OraSure test.

Currently, there are no other HIV Ora test on the market.

The Health Department uses this device for all of our street outreach activities and community-based partnerships because it is a less invasive procedure. In the past, the program has drawn blood in the field, however felt this was a much safer form of practice and yielded better results in the number of people consenting to test. The procedure is simple and requires minimal training.

I hope this addresses the board concerns. If you desire additional information, please do not hesitate to call me at 747-0128 or email me.

Janice Johnson, Director
Chicago Department of Public Health
STD/HIV Prevention and Care Program

S. S. R. B.

DATE July 11, 2002
APPROVED... 4-0
CONDITIONALLY APPROVED....
RETURN TO DEPT....
DISAPPROVED....
April 16, 2002

Chicago Dept of Health
530 E 31ST St.
# 4124
Chicago, IL 60621

To Whom It May Concern,

OraSure Technologies, Inc. is the only licensed manufacturer and distributor of the OraSure® HIV-1 Oral Specimen Collection Device (503-0050). If you need any further information please feel free to contact me at 1-800-869-3538.

Best Regards,

Joanne Hannabery
OraSure Technologies, Inc.
Sr. Manager, Client Services
Frank Oldham, Jr.
Chicago Department of Health
333 South State, 2nd Floor
Chicago, IL 60604-3972

Reference: Cooperative Agreement Number U62/CCU504523-12-4, HIV Prevention Project

Dear Mr. Oldham:

Enclosed is Amendment No. 4 to the above referenced cooperative agreement, the purpose of which is to award Financial Assistance in supplemental funds of $958,900 in accordance with the Terms and Conditions specified in the enclosed Notice of Cooperative Agreement. This amendment also changes the ending date for the project period to December 31, 2003, which reflect the five-year project period stipulation in the Program Announcement 99004.

All other terms and conditions in the original award document and any amendments remain in full force unless rescinded in writing by the Grants Management Officer.

If you have any questions on this matter, please feel free to contact Peaches Brown, Grants Management Specialist, 770-488-2738.

Sincerely,

Ron Van Duyne
Grants Management Officer
Grants Management Branch

Enclosure

cc: Business Office
REMARKS

This amendment changes the ending date for the project period to December 31, 2003, which reflect the five-year project period stipulation in the Program Announcement 99004.

NOTE 1: SUPPLEMENTAL FUNDING

Pursuant to your request for supplemental funding in your application dated May 15, 2001, funds are awarded in the categories indicated below.

<table>
<thead>
<tr>
<th>Budget Categories</th>
<th>Part I Amount</th>
<th>Part II Amount</th>
<th>Total Supplement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salaries &amp; Wages</td>
<td>$</td>
<td>$ 82,770</td>
<td>$ 82,770</td>
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<tr>
<td>Fringe Benefits</td>
<td></td>
<td>21,624</td>
<td>21,624</td>
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<td>Consultant Costs</td>
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</tr>
<tr>
<td>Equipment</td>
<td>$ 131,855</td>
<td>$ 2,000</td>
<td>$ 133,855</td>
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<tr>
<td>Supplies</td>
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<td>3,000</td>
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<tr>
<td>Travel</td>
<td></td>
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</tr>
<tr>
<td>Other</td>
<td></td>
<td>35,408</td>
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<tr>
<td>Contractual</td>
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<td>558,482</td>
<td>558,482</td>
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<tr>
<td>Total Direct Costs</td>
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<td>$ 706,784</td>
<td>$ 838,639</td>
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<tr>
<td>Indirect Costs</td>
<td>18,908</td>
<td>101,353</td>
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<td>Total Costs</td>
<td>$ 150,763</td>
<td>$ 808,137</td>
<td>$ 958,900</td>
</tr>
</tbody>
</table>

Part I: Existing HIV Prevention Programs
Part II: Evaluation Activities Base

NOTE 2: RESTRICTIONS

Note that all costs, including contracts or subcontracts, must be described in adequate detail to avoid restrictions. Adequate detail consists of the breakout of all totals or subtotals into the cost categories presented in the table included above, along with sufficient information to permit a diligent review of the allowability of the costs (including reasonableness and allocability) under the applicable Federal Cost Principals.

→LINE ITEM COST DETAIL (actual or estimated) FOR ALL CONTRACTS IS REQUIRED TO BE SUBMITTED TO THE CDC GRANTS OFFICE WITHIN 60 DAYS OF THE DATE OF THIS AWARD TO AVOID FURTHER RESTRICTION OF THE FUNDS. Additionally, you must specify for all contracts the method of selection, period of performance, and a summary of the contract objectives and obligations. Sole source contracts must be adequately justified to be permitted under federal procurement standards. It is noted none of the above required data for Contractual items were submitted with your application. Please provide all the required details to avoid restriction of all Contractual funds.

Please submit further justification and detailed information to allow a determination that costs requested are allowable, allocable, reasonable and necessary, in the following budget categories.
as indicated in your budget justification: Out of Town Travel, Local Transportation, Books & Related Materials, Stationery & Office Supplies, Computer Hardware, Advertising, and Technical Meeting Costs.

NOTE 3: TERMS AND CONDITIONS

All other terms and conditions of the original award remain unchanged and in full effect.
IMPORTANT REMINDER!

The awardee is reminded that all written materials, audiovisual materials, pictorials, questionnaires, survey instruments, educational curricula and other relevant program materials have to be reviewed and approved by an established program review panel.

Any CDC funds used to indirectly award Community Based Organizations (CBOs) fall under these guidelines.

IMPORTANT REMINDER!
CITY OF CHICAGO
BASE TERM AGREEMENT

AGREEMENT NUMBER: B24952601
DESCRIPTION: COLLECTION DEVICE HIV-1 ORAL SPECIMEN
GROUP:
CONTRACT ADMIN: 53 ODELL BROWN 312-744-9806
NUMBER OF LINES: 1

<table>
<thead>
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<th>LINE</th>
<th>COMMODITY/DESCRIPTION</th>
<th>LOT ORDER</th>
<th>UNIT OF MEASURE</th>
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<tbody>
<tr>
<td>0010</td>
<td>HIV-1 ORAL SPECIMEN</td>
<td>168</td>
<td>CS</td>
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</tbody>
</table>

COLLECTION DEVICE, ORASURE NO. 503-0050

ACCOUNTING INFORMATION
BFRYR FUND DEPT ORGN APPR ACTV OBJECT RPTG JOB/PROJ
41 DEPARTMENT OF HEALTH 02 315 41 3355 0342 0342 T010
# OraSure Test Kits

<table>
<thead>
<tr>
<th>ITEM NO.</th>
<th>QUANTITY PER CASE</th>
<th>PRICE/KIT</th>
<th>CASE PRICE</th>
</tr>
</thead>
<tbody>
<tr>
<td>503-1025</td>
<td>25 Testing Kits (25 mailers to lab)</td>
<td>$25.35</td>
<td>$633.75</td>
</tr>
<tr>
<td>or 503-2025</td>
<td>Individually Packaged Kits Including Laboratory Processing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>503-1100</td>
<td>100 Testing Kits (40 mailers to lab)</td>
<td>$22.05</td>
<td>$2,205.00</td>
</tr>
<tr>
<td>or 503-2100</td>
<td>Bulk Packaged Kits Including Laboratory Processing</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
FEA TURES

...OraSure is an oral fluid collection system that is free from the risk of needles & blood;
...The OraSure Test Kit includes a collection device, express mailer, and all required laboratory testing;
...Test results are provided 3 working days after receipt at the laboratory;
...Collected specimens are stable for 21 days at 39°F to 98°F;
...FDA approved.

BENEFITS

SAFE: Eliminates the risk of needle stick injuries;
CONVENIENT: Easily transportable in the field;
COST EFFECTIVE: Includes both EIA Screen & Western Blot confirmatory testing;
RAPID TURNAROUND TIME: Results returned in about 3 days; fewer patients lost to follow-up;
PORTABLE: Can be done virtually anywhere; no biohazard waste;
ACCURATE: Greater than 99% accuracy.

TO PLACE AN ORDER
Please telephone or fax OraSure Technologies’ Customer Service Department (numbers below) and provide the following information:
1) Credit Information (if new customer);
2) Item No. you wish to order;
3) Quantity of the item you wish to order;
4) Your Purchase Order number;
5) SHIP TO address;
6) BILL TO address;
7) Contact names.

TERMS & CONDITIONS

• Payment terms are Net 30. FOB OraSure Technologies, Inc. freight billed. Federal ID# 36-4370966.
• Order subject to approval by OraSure Technologies, Inc. Quote is valid for orders placed within 30 days.
• A credit application must be on file, and the purchasing physician must receive the “Dear Doctor” letter before shipping OraSure.
• PO’s should be addressed to: OraSure Technologies, Inc., Attn: Customer Service, 150 Webster Street, Bethlehem, PA 18015.
• Send payments to: OraSure Technologies, Inc., Accounts Receivable, 150 Webster Street, Bethlehem, PA 18015.
• Returns allowed only on defective or incorrect product. Prior approval must be obtained. Expired product specifically excluded.
• Product is not available for resale or commercial distribution without proper authorization from OraSure Technologies, Inc.
• Prices subject to change without notice.

OraSure Technologies, Inc.
Customer Service Department
150 Webster Street, Bethlehem, Pennsylvania 18015
Telephone 800.869.3538 • Facsimile 610.882.3572

BRIEF SUMMARY OF IMPORTANT INFORMATION. See package insert for complete information. OraSure® HIV-1 Oral Specimen Collection Device is intended for use in the collection of oral fluid specimens for testing for antibodies to the Human Immunodeficiency Virus Type 1 (HIV-1) is intended for use in patients 13 years of age or older. Indications: • The administration of this device is restricted to individuals who have been trained in the use of this device. • The device is not to be provided to subjects for home use. • Testing of OraSure HIV-1 oral fluid specimens is restricted to testing with the OraSure HIV-1 System manufactured by OraSure Technologies, Inc.

Legal Information: OraSure is a registered trademark of OraSure Technologies, Inc. VerioKits is a registered trademark of Organo Teknika Corporation.
Abstract 403

TITLE: Oral Fluid Testing*: Breaking Down Barriers to Testing
AUTHORS: Bauserman, RL; Ward, MA; Christmyer, CS (Maryland Department of Health and Mental Hygiene)

BACKGROUND/OBJECTIVES: The state of Maryland sought to increase access and utilization of HIV testing and counseling services (CTS) with an oral fluid test demonstration project in 1997-98. A number of clients who agreed to oral testing indicated that they would not have been tested if the oral option was unavailable (blood-test avoiders). This population was compared to other testers (who indicated that they would have tested even without the oral option) to characterize differences and similarities.

METHODS: Participants in the oral fluid testing demonstration project completed a client survey assessing responses to the test (n = 1432). Of these clients, 302 (21.1%) agreed or strongly agreed that they would not have been tested if the oral option had not been available. These blood-test avoiders (BTAs) were compared to others who completed the test on the basis of seropositivity, previous testing, demographic characteristics, and risk factors.

RESULTS: The BTAs did not differ in seropositivity from others who received the oral test (1.7% vs. 1.8%). Only 49.6% of BTAs, vs. 69.6% of other testers, had been tested previously. For most risk factors, there was no difference between BTAs and other testers. However, male BTAs were less likely than other male testers to report injecting drug use (p = .045), sex with and IDU (p = .033), or sex while high or drunk (p = .002). Female BTAs were less likely than other female testers to report sex with a person with “other” AIDS risk (p = .018) or being a victim of sexual assault (p = .032), and more likely to report “no acknowledged risk” (p = .006). Comparison of demographic characteristics revealed that males were more likely than females to be either BTAs or uncertain about whether they would have tested without the oral option (41.1% vs. 33.5%). African Americans appeared more likely than Caucasians to be either BTAs or uncertain about testing without the oral option (41.9% vs. 33.3%). Clients aged 20-29 had the lowest proportion of BTAs (17.3%).

CONCLUSIONS: Although some risk factors are less characteristic of BTAs than other testers, the two groups do not differ in seropositivity. To the extent that BTAs, or those uncertain about testing, are also more likely to be male or African American, oral testing helps increase testing in groups that are disproportionately affected by HIV in Maryland. Oral testing appears to be a viable option for reaching at-risk individuals who otherwise would have refused or avoided testing, and identifying seropositive individuals who may otherwise not have been tested.

*The oral fluid test used in this research was OraSure®.

PRESENTER CONTACT INFORMATION

Name: Robert Bauserman
Address: AIDS Administration, DHMH
500 N. Calvert Street
Baltimore, MD 21202
Telephone: (410) 767-4322
Fax: (410) 333-6333
E-mail: bausermanr@dhmh.state.md.us
OraSure a Valuable Asset to HIV Prevention

The Bureau of HIV/AIDS has been providing Florida counseling and testing programs with OraSure Oral HIV-1 Antibody Testing Systems since February 1998. To receive OraSure, providers must complete a request form documenting their need, proposed usage, and target populations. This testing method, which tests for antibodies in oral mucosal transudate, is as accurate as a blood test for diagnosis in public health and clinical settings. In Florida, OraSure is primarily used in outreach settings to reach high-risk persons who are less likely to access health care systems and less accepting of conventional testing methods (e.g., homeless persons, drug abusers, youth, and rural populations).

- In the past two years (April 1, 1999—March 31, 2001), 481,533 HIV tests were administered at registered HIV counseling and testing sites in Florida. Of these, 80,563 (16.7%) were conducted with OraSure. Sites using OraSure identified 2,120 positive tests in this period, and the resulting statewide positivity rate (2.6%) was higher than that reported for blood tests alone (2.1%).

- 36.8% of OraSure tests in this period were administered anonymously. Community-based organizations (CBOs) performed the majority of anonymous OraSure tests (19,246, or 64.9%); county health departments conducted 8,740 (29.5%). Positivity rates were nearly the same—2.8% for CBOs and 2.9% for CHDs. While the volume was small (less than 1,000 tests), private sites utilizing the state laboratories for test processing also reported a high positivity rate for anonymous OraSure tests (5.8%).

- The volume of confidential OraSure testing was highest at drug treatment facilities (14,645, or 18.2%) and CBOs (12,173, or 15.1%). Positivity rates were highest at CBOs (3.9%) and STD clinics (3.6%).

- Two counties—Miami-Dade and Duval—accounted for nearly 40% of all OraSure testing between April 1999 and March 2001. Other high volume users included Orange, Hillsborough, Palm Beach, and Broward. 36 counties conducted at least 100 OraSure tests in this period. In 19 of those counties, higher relative positivity rates were found with OraSure as compared to blood tests. Figure 1 compares the positivity rates in these 19 counties. The largest differences between blood and OraSure testing were discovered in Putnam, Sarasota, Leon, Okaloosa, and Volusia counties.

- Of the 80,563 OraSure tests conducted in this period, non-Hispanic blacks accounted for 42.4% (34,165), as compared to non-Hispanic whites (30,783, or 38.2%) and Hispanics (11,268, or 14.0%). Blacks also had the highest positivity rate (3.9%), followed by Hispanics (2.0) and whites (1.4%).

For additional information about these HIV data, contact Marlene LaLota, MPH, or Melinda Waters at (850) 245-4424 or SunCom 205-4424, or visit our website at http://www.doh.state.fl.us/disease_CTRL/aids.
Abstract 690


AUTHORS: Randall, LM; Pope RS; Ives, E (Michigan Department of Community Health, Lansing); Lapinski, MK (Michigan State University, East Lansing); Hunt, KV; Branson, BR (Centers for Disease Control and Prevention, Atlanta).

BACKGROUND/OBJECTIVES: The Michigan Department of Community Health implemented HIV testing, using oral mucosal transudate (OMT) technology, in community-based settings in March 1997. Implementation of OMT-based HIV testing was intended to enhance access and acceptability of HIV testing in at-risk populations. An evaluation of the OMT initiative was undertaken to assess: (1) the extent to which OMT technology increased use of HIV testing among at-risk populations and (2) cost-effectiveness of OMT-based testing.

METHODS: In-depth interviews with clients and providers were conducted to obtain descriptive information related to the context in which HIV testing services are offered; client preferences related to HIV counseling and testing services, including perceived disincentives to use of such services and provider preferences related to HIV counseling and testing services. Analysis of data included comparisons of settings and client/provider preferences for OMT and serum-based testing. HIV testing service data was analyzed for patterns in utilization among priority populations. Analysis included comparison of OMT and serum-based testing. Cost-effectiveness of OMT testing was estimated for the number of HIV+ and HIV- individuals who learned their HIV serostatus.

RESULTS: Of approximately 60,000 tests conducted annually in Michigan, approximately 25 percent are now conducted using OMT technology. Among clients tested using OMT, one percent are found to be HIV infected compared with 0.5 percent of those tested using serum-based technology. Among all clients tested using OMT, three-quarters are a high-risk @ (e.g. MSM, IDU and sex partners at-risk/infected individuals) compared with one quarter of individuals tested using serum. Use of HIV testing services increased by 150 percent among IDUs, 60 percent among African American and 30 percent among Latinos. Overall, 75 percent of clients tested using OMT returned for test results compared with 65 percent of those tested using serum. There was no difference return rate according to testing method among HIV seropositive individuals. OMT-based testing for HIV seropositives costs approximately $34.46 compared with $31.62 for HIV seropositives tested using serum. The cost of OMT-based testing for seronegatives is $16.16 compared with $17.22 for seronegative individuals tested using serum. Because the majority of tests conducted with OMT are HIV seronegative, OMT results in a substantial cost-savings compared with serum-based testing.

CONCLUSIONS: OMT has facilitated provision of prevention services in community-based settings. Use of OMT-based testing has effectively addressed client preferences for HIV testing and removed practical disincentives to HIV testing in priority populations. OMT is a cost-effective method of providing HIV counseling and testing services.

PRESENTER CONTACT INFORMATION

Name: Lisa M. Randall
Address: HIV/AIDS Prevention & Intervention Section
Michigan Department of Community Health
P. O. Box 30195
Lansing, MI 48909
Telephone: (517) 335-8012
Fax: (517) 335-9611
E-mail: rand106w@cdc.gov
OraSure®
Oral HIV-1 Antibody Test

FEATURES

...OraSure is an oral fluid collection system that is free from the risk of needles & blood;
...The OraSure Test Kit includes a collection device, express mailer, and all required laboratory testing;
...Test results are provided 3 working days after receipt at the laboratory;
...Collected specimens are stable for 21 days at 39°F to 98°F;
...FDA approved.

BENEFITS

SAFE: Eliminates the risk of needle stick injuries;
CONVENIENT: Easily transportable in the field;
COST EFFECTIVE: Includes both EIA Screen & Western Blot confirmatory testing;
RAPID TURNAROUND TIME: Results returned in about 3 days; fewer patients lost to follow-up;
PORTABLE: Can be done virtually anywhere; no biohazard waste;
ACCURATE: Greater than 99% accuracy.

TO PLACE AN ORDER

Please telephone or fax OraSure Technologies' Customer Service Department (numbers below) and provide the following information:
1) Credit Information (if new customer);
2) Item No. you wish to order;
3) Quantity of the item you wish to order;
4) Your Purchase Order number;
5) SHIP TO address;
6) BILL TO address;
7) Contact names.

TERMS & CONDITIONS

• Payment terms are Net 30. FOB OraSure Technologies, Inc. freight billed. Federal ID# 36-4370966.
• Order subject to approval by OraSure Technologies, Inc. Quote is valid for orders placed within 30 days.
• A credit application must be on file, and the purchasing physician must receive the "Dear Doctor" letter before shipping OraSure.
• PO's should be addressed to: OraSure Technologies, Inc., Attn: Customer Service, 150 Webster Street, Bethlehem, PA 18015.
• Send payments to: OraSure Technologies, Inc., Accounts Receivable, 150 Webster Street, Bethlehem, PA 18015.
• Returns allowed only on defective or incorrect product. Prior approval must be obtained. Expired product specifically excluded.
• Product is not available for resale or commercial distribution without proper authorization from OraSure Technologies, Inc.
• Prices subject to change without notice.

OraSure Technologies, Inc.
Customer Service Department
150 Webster Street, Bethlehem, Pennsylvania 18015
Telephone 800.869.3538 • Facsimile 610.882.3572

BRIEF SUMMARY OF IMPORTANT INFORMATION. See package insert for complete information. OraSure® HIV-1 Oral Specimen Collection Device is intended for use in the collection of oral fluid specimens for testing for antibodies to the Human Immunodeficiency Virus Type 1 (HIV-1) in subjects 13 years of age or older. Misuse of device • The administration of the device is restricted to individuals who have been trained in the use of this device. • The device is not to be provided to subjects for home use. • Testing of OraSure HIV-1 and Rapid HCV specimens is restricted to testing with the Oral Fluid Verigene® HIV-1 HCV System manufactured by Verigene Technologies Corporation and the OraSure HIV-1 Western Blot Kit manufactured by OraSure Technologies, Inc. • The OraSure HIV-1 device is restricted to use for diagnostic purposes and must not be used to screen blood donors.

Importation of Device • If a subject tests repeatedly reactive with the Oral Fluid Verigene® HIV-1 HCV System, he or she should be further tested for HIV-1 antibodies with the more specific OraSure HIV-1 Western Blot Kit. • OraSure specimens should be properly handled, shipped, and stored. OraSure is the registered trademark of OraSure Technologies, Inc. Verigene is the registered trademark of Verigene Technologies Corporation.
TITLE: Oral Fluid Testing*: Breaking Down Barriers to Testing
AUTHORS: Bauserman, RL; Ward, MA; Christmyer, CS (Maryland Department of Health and Mental Hygiene)

BACKGROUND/OBJECTIVES: The state of Maryland sought to increase access and utilization of HIV testing and counseling services (CTS) with an oral fluid test demonstration project in 1997-98. A number of clients who agreed to oral testing indicated that they would not have been tested if the oral option was unavailable (blood-test avoiders). This population was compared to other testers (who indicated that they would have tested even without the oral option) to characterize differences and similarities.

METHODS: Participants in the oral fluid testing demonstration project completed a client survey assessing responses to the test (n = 1432). Of these clients, 302 (21.1%) agreed or strongly agreed that they would not have been tested if the oral option had not been available. These blood-test avoiders (BTAs) were compared to others who completed the test on the basis of seropositivity, previous testing, demographic characteristics, and risk factors.

RESULTS: The BTAs did not differ in seropositivity from others who received the oral test (1.7% vs. 1.8%). Only 49.6% of BTAs, vs. 69.6% of other testers, had been tested previously. For most risk factors, there was no difference between BTAs and other testers. However, male BTAs were less likely than other male testers to report injecting drug use (p = .045), sex with and IDU (p = .033), or sex while high or drunk (p = .002). Female BTAs were less likely than other female testers to report sex with a person with “other” AIDS risk (p = .018) or being a victim of sexual assault (p = .032), and more likely to report “no acknowledged risk” (p = .006). Comparison of demographic characteristics revealed that males were more likely than females to be either BTAs or uncertain about whether they would have tested without the oral option (41.1% vs. 33.5%). African Americans appeared more likely than Caucasians to be either BTAs or uncertain about testing without the oral option (41.9% vs. 33.3%). Clients aged 20-29 had the lowest proportion of BTAs (17.3%).

CONCLUSIONS: Although some risk factors are less characteristic of BTAs than other testers, the two groups do not differ in seropositivity. To the extent that BTAs, or those uncertain about testing, are also more likely to be male or African American, oral testing helps increase testing in groups that are disproportionately affected by HIV in Maryland. Oral testing appears to be a viable option for reaching at-risk individuals who otherwise would have refused or avoided testing, and identifying seropositive individuals who may otherwise not have been tested.

*The oral fluid test used in this research was OraSure®.

PRESENTER CONTACT INFORMATION

Name: Robert Bauserman
Address: AIDS Administration, DHMH
500 N. Calvert Street
Baltimore, MD 21202
Telephone: (410) 767-4322
Fax: (410) 333-6333
E-mail: bausermanr@dhmh.state.md.us
OraSure a Valuable Asset to HIV Prevention

The Bureau of HIV/AIDS has been providing Florida counseling and testing programs with OraSure Oral HIV-1 Antibody Testing Systems since February 1998. To receive OraSure, providers must complete a request form documenting their need, proposed usage, and target populations. This testing method, which tests for antibodies in oral mucosal transudate, is as accurate as a blood test for diagnosis in public health and clinical settings. In Florida, OraSure is primarily used in outreach settings to reach high-risk persons who are less likely to access health care systems and less accepting of conventional testing methods (e.g., homeless persons, drug abusers, youth, and rural populations).

- In the past two years (April 1, 1999—March 31, 2001), 481,533 HIV tests were administered at registered HIV counseling and testing sites in Florida. Of these, 80,563 (16.7%) were conducted with OraSure. Sites using OraSure identified 2,120 positive tests in this period, and the resulting statewide positivity rate (2.6%) was higher than that reported for blood tests alone (2.1%).

- 36.8% of OraSure tests in this period were administered anonymously. Community-based organizations (CBOs) performed the majority of anonymous OraSure tests (19,246, or 64.9%); county health departments conducted 8,740 (29.5%). Positivity rates were nearly the same—2.8% for CBOs and 2.9% for CHDs. While the volume was small (less than 1,000 tests), private sites utilizing the state laboratories for test processing also reported a high positivity rate for anonymous OraSure tests (5.8%).

- The volume of confidential OraSure testing was highest at drug treatment facilities (14,645, or 18.2%) and CBOs (2,173, or 15.1%). Positivity rates were highest at CBOs (3.9%) and STD clinics (3.6%).

- Two counties—Miami-Dade and Duval—accounted for nearly 40% of all OraSure testing between April 1999 and March 2001. Other high volume users included Orange, Hillsborough, Palm Beach, and Broward. 36 counties conducted at least 100 OraSure tests in this period. In 19 of those counties, higher relative positivity rates were found with OraSure as compared to blood tests. Figure 1 compares the positivity rates in these 19 counties. The largest differences between blood and OraSure testing were discovered in Putnam, Sarasota, Leon, Okaloosa, and Volusia counties.

- Of the 80,563 OraSure tests conducted in this period, non-Hispanic blacks accounted for 42.4% (34,165), as compared to non-Hispanic whites (30,763, or 38.2%) and Hispanics (11,268, or 14.0%). Blacks also commanded the highest positivity rate (3.9%), followed by Hispanics (2.0) and whites (1.4%).

![Figure 1. Florida Counties Showing Increased Positivity Rates When Using OraSure, April 1999-March 2001](image)

![Figure 2. OraSure HIV Tests and Seropositivity Rates in Florida by Race/Ethnicity, April 1999-March 2001](image)

For additional information about these HIV data, contact Marlene LaLota, MPH, or Melinda Waters at (850) 245-4424 or SunCom 205-4424, or visit our website at http://www.doh.state.fl.us/disease_ctrl/aids.
Abstract 690


AUTHORS: Randall, LM; Pope RS; Ives, E (Michigan Department of Community Health, Lansing); Lapinski, MK (Michigan State University, East Lansing); Hunt, KV; Branson, BR (Centers for Disease Control and Prevention, Atlanta).

BACKGROUND/OBJECTIVES: The Michigan Department of Community Health implemented HIV testing, using oral mucosal transudate (OMT) technology, in community-based settings in March 1997. Implementation of OMT-based HIV testing was intended to enhance access and acceptability of HIV testing in at-risk populations. An evaluation of the OMT initiative was undertaken to assess: (1) the extent to which OMT technology increased use of HIV testing among at-risk populations and (2) cost-effectiveness of OMT-based testing.

METHODS: In-depth interviews with clients and providers were conducted to obtain descriptive information related to the context in which HIV testing services are offered; client preferences related to HIV counseling and testing services, including perceived disincentives to use of such services and provider preferences related to HIV counseling and testing services. Analysis of data included comparisons of settings and client/provider preferences for OMT and serum-based testing. HIV testing service data was analyzed for patterns in utilization among priority populations. Analysis included comparison of OMT and serum-based testing. Cost-effectiveness of OMT testing was estimated for the number of HIV+ and HIV- individuals who learned their HIV serostatus.

RESULTS: Of approximately 60,000 tests conducted annually in Michigan, approximately 25 percent are now conducted using OMT technology. Among clients tested using OMT, one percent are found to be HIV infected compared with 0.5 percent of those tested using serum-based technology. Among all clients tested using OMT, three-quarters are a high-risk @ (e.g. MSM, IDU and sex partners) compared with one quarter of individuals tested using serum. Use of HIV testing services increased by 150 percent among IDUs, 60 percent among African American and 30 percent among Latinos. Overall, 75 percent of clients tested using OMT returned for test results compared with 65 percent of those tested using serum. There was no difference return rate according to testing method among HIV seropositive individuals. OMT-based testing for HIV seropositives costs approximately $34.46 compared with $31.62 for HIV seropositives tested using serum. The cost of OMT-based testing for seronegatives is $16.16 compared with $17.22 for seronegative individuals tested using serum. Because the majority of tests conducted with OMT are HIV seronegative, OMT results in a substantial cost-savings compared with serum-based testing.

CONCLUSIONS: OMT has facilitated provision of prevention services in community-based settings. Use of OMT-based testing has effectively addressed client preferences for HIV testing and removed practical disincentives to HIV testing in priority populations. OMT is a cost-effective method of providing HIV counseling and testing services.

PRESENTER CONTACT INFORMATION

Name: Lisa M. Randall
Address: HIV/AIDS Prevention & Intervention Section
         Michigan Department of Community Health
         P. O. Box 30195
         Lansing, MI 48909
Telephone: (517) 335-8012
Fax: (517) 335-9611
E-mail: rand106w@cdc.gov
QUOTE

ORDER NUMBER: 0201794
ORDER DATE: 3/28/2002

SALESPERSON: YWAR
CUSTOMER NO: CHICAGO

SHIP TO:
CHICAGO DEPT. OF PUBLIC HEALTH
BHV 0141-114535 FOR PMT
333 S STATE

CHICAGO,
IL 60604

CONFIRM TO: LINDA PARKS
Phone Number: 

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ORASURE HIV-1 50 CT CASE

QUANTITY INCLUDES SHIPMENTS TWICE YEARLY

PRICE QUOTE ONLY
PRICE PER CASE INCLUDES GROUND
TRANSPORTATION TO CHICAGO
QUOTE IS FOR A 2 YEAR PERIOD FROM
07/01/2002 THROUGH 06/30/2004

S. S. R. B.

DATE July 11, 2002
APPROVED... 4-0

CONDITIONALLY
APPROVED...

RETURN TO DEPT...
DISAPPROVED...

Net Order: 43,120.00
Less Discount: 0.00
Freight: 0.00
Sales Tax: 0.00
43,120.00
June 10, 2004

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

SUBJECT: Quote for OraQuick® Rapid HIV-1 Test Devices and Controls

Dear Mr. Lakosky:

OraSure Technologies, Inc. (OTI) is pleased to provide the below listed price quote for OraQuick® Rapid HIV-1 Test Devices and Controls.

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<td>1001-0052</td>
<td>OraQuick® Rapid HIV-1, 25 ct</td>
<td>$20.00 each</td>
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<td>1001-0051</td>
<td>OraQuick® Rapid HIV-1, 100 ct</td>
<td>$20.00 each</td>
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<td>1001-0049</td>
<td>OraQuick® Rapid HIV Control</td>
<td>$20.00 set</td>
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*1 set of controls will cover approximately 25 tests.
**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 5-7 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).

Training
OTI will provide training at no additional cost which will cover item's such as: product information, step by step instructions for use of product, reading and interpreting test results, frequently asked questions regarding OraQuick® Rapid HIV-1 Antibody Tests as well as questions from individuals attending the training. Additional information as well as a training video will be provided at the training session.

This quote will remain valid for orders placed with in 30 days. Should you require additional information, please contact Tom Pavlowski, Account Manager, Infectious Disease Testing at 610-509-0177 or 800-869-3538, ext. 3288.

Regards,

[Signature]
Patricia Reis
Contract Administrator
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**Comments:**
- Kit 100 test kits
- Human Immunodeficiency Virus (HIV) 03/19524420
- Kit HIV-1 Oligonucleotide DNA Primer 03/19524420
- Human Immunodeficiency Virus (HIV) DNA 03/19524420
- Kit HIV-1 Oligonucleotide DNA Primer 03/19524420
### CITY OF CHICAGO

**PURCHASE REQUISITION**

**DELIVER TO:**
041-3350 DEPAUL 2FL
333 S. STATE ST.
2ND FLOOR
Chicago, IL 60604

**REQUISITION:** 13758
**PAGE:** 1
**DEPARTMENT:** 41 - DEPARTMENT OF HEALTH
**PREPARER:** Maribel E Valdez
**NEEDED:**
**APPROVED:** 4/22/2004

### REQUISITION DESCRIPTION
TO ADD LINE ITEMS TO EXISTING CONTRACT FOR ORASURE PO 2308
SPECIFICATION NUMBER: 11577

### COMMODITY INFORMATION

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**REQUISITION TOTAL:** 0.00

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Where a commodity is for a particular or unique use other than standard quality, grades, 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.
PROJECT CHECKLIST

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: 4/23/04
ID No. (Spec, RX, Project): 2308
Department: #41 Health
Bureau: HIV/AIDS
Contact Person: Maribel Valdez
Tel: 7-8828 Fax: 7/1031 E-mail: 
Project Manager: Janice Johnson
Tel: 7-0128 Fax: 7-9663 E-mail: 
Contract No.(if known New Contract) Estimated Value $108,000
Project Title/Description: To add lines to contact 2308 OraSure Technologies, Inc. We already added over the limit a total of $108,000.

SCOPE STATEMENT
___ 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 ___Sole Source X Term Agreement ___One Shot
___ Mod/Amendment ___Time Extension ___Additional Funding ___Small Order ___ S/O Emergency
FORMS
___ F-25* (add line items) X F-10 *(special approval) ___SSRB**(SOLE SOURCE REQUEST)
___ F-26* (new term agreement) ___RX (one-shot requisition) ___ OBM Authorization
___ F-27* (time extension) ___ 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: ___Corporate ___Bond ___Enterprise X Grant* ___ Other
State: ___IDOT/Transit ___IDOT/Highway ___Grant* ___ Other
Federal: ___FHWA ___FTA ___FAA ___Grant* ___ Other
Funding Strips: 03-260-41-3355-0300-0342-Y401 and 03-050-41-3350-0300-0342-A140

___Attach copy of applicable grant agreement terms and conditions language:

TIME FRAME
Date Needed: 4/30/04 Requested
Contract Term (y/m/d): 1/01/03-12/31/04

PRE BID/SUBMITTAL REQUIREMENTS
Requesting Pre Bid/Submitittal Conference? ___Yes ___No Requesting Pre Bid/Submitittal be Mandatory? ___Yes ___No
Requesting Site Visit? ___Yes ___No Requesting Site Visit be Mandatory? ___Yes ___No

Form Date: 1/16/2002
MEMORANDUM

TO: Eric J. Griggs
    Chief Procurement Officer

FROM: John L. Wilhelm, M.D., MPH
      Department of Public Health Commissioner

DATE: June 10, 2004

ATTN: SOLE SOURCE BOARD _ Staci Stewart

SUBJECT: Justification for adding new lines
to HIV Oral Specimen Collection Devices
Sole Source Contract

This letter serves as a confirmation to add three lines to the existing
Orasure PO # 2308 with Spec # 11577. Please note that the
justification for adding these three lines is to meet the needs of the
program coordinating HIV testing for new clients.
Furthermore, these three items were not included in the previous contract.
The following are the three lines to be added:

1935244110 Human Immunodeficiency virus type I & II kits – Rapid
HIV-1 Oraquick 1001-0051, 100 CT.

1935244100 Human Immunodeficiency virus type I & II kits – Rapid
HIV-1 Oraquick 1001-0052, 25 CT.

1935244125 Human Immunodeficiency virus type I & II kits – Rapid
HIV-1 Oraquick 1001-0049, 50 Set.

Please find a copy of the sole source justification, as well as the current
Contractor’s Quote for the three line items described above, dated June

Please do not hesitate to contact Mauricio Beltran at (312) 747-9658,
should you have any questions concerning the above.

Thank you greatly for your assistance in procurement matters.

cc: Peg White
    Maribel Valdez
    Mauricio Beltran
### City of Chicago Department of PROCUREMENT SERVICES

**Spec #:** 824952601  
**Description:** HIV ORAL SPECIMEN COLLECTION DEVICES

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**Total Procurement Cycle Time (Days):** 80

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**INTER-DEPARTMENT NOTICE OF CONTRACT AWARD**

**CITY of CHICAGO**

**DEPARTMENT of PROCUREMENT SERVICES**

**CITY HALL, 121 N. LaSALLE, ROOM 403**

CHICAGO, IL 60602

Attached are copies of contract documents related to an award in which your department has been included. These copies provide basic information related to the subject award. Please refer to EPS for additional information concerning this agreement, if required. The notice replaces (Rev. 5/95)

(Rev. 6/02)

171540-frm-26-6