

REQUEST FOR SOLE SOURCE



STATE PROCUREMENT OFFICE
NOTICE & REQUEST FOR SOLE SOURCE

11 DEC 19 8:56

STATE PROCUREMENT OFFICE
 STATE OF HAWAII

TO: Chief Procurement Officer
 FROM: Health/State Laboratories/Medical Microbiology Branch
Name of Requesting Department

Pursuant to HRS §103D-306, and Subchapter 9, HAR Chapter 3-122, the Department requests sole source approval to purchase the following:

1. Describe the goods, services, or construction to be procured.
 Human Immunodeficiency Virus Oral Fluid Test Kits & Oral Fluid Specimen Collection Devices

2. Vendor/Contractor Name: Orasure Technologies, Inc.	3. Amount of Request: \$ 100,000 20,000 <i>AK 1/26/12</i>
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4. Term of contract (shall not exceed 12 months), if applicable: From: 1/28/2012 To: 1/27/2013	5. Prior Sole Source Ref No.: 11-022-D
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6. Features: Describe in detail the unique features, characteristics, or capabilities of the goods, services or construction. OraSure Technologies, Inc. is the manufacturer of the only known USFDA approved supplemental/confirmatory test for confirmation of oral fluid specimens for the presence of antibodies to Human Immunodeficiency Virus (HIV) Type 1. This product is unique in that it enables testing oral fluids for the presence or absence of antibodies to HIV. The testing of alternative specimens to blood and serum allows the collection of specimens in non-traditional settings. Many of these alternative specimens can be collected via non-invasive techniques. This allows counseling and specimen collection to be done by individuals who do not require specialized training for the collection of blood via venipuncture which requires specialized training. (Continued on page 4.)

7. Essential features: Describe in detail how the unique features, characteristics, or capabilities of the goods, services, or construction are essential for the department to accomplish its work. The use of alternative specimens for the presence or absence of HIV related antibodies, enables the control program of the health department to enter into non-traditional Counseling and Testing venues. Traditionally, these locations have been in health care clinics and medical settings. The use of oral fluid based test allows for the collection of specimens in just about any location. The procedure is non-invasive and allows for the collection of specimens, without concern about potential sharps and the inherent concern for blood-borne pathogens. The ability to extend specimen collection beyond the normal boundaries, has enhanced the ability for the control program to extend testing into areas that have been previously inaccessible. (Continued on page 4.)

8. Describe the efforts and results in determining that this is the only vendor/contractor who can provide the goods, services or construction. OraSure Technologies, Inc. is the manufacturer of the only known USFDA approved manufacturer and supplier of oral fluid collection devices and supplemental/confirmatory test. National studies have indicated that the use of oral fluids yields better sensitivity and specificity for HIV antibodies, than other alternative body fluids, such as urine.

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9. Alternate source. Describe the other possible sources for the goods, services, or construction that were investigated but did not meet the department's needs.
 No other alternate sources.

10. Identify the primary individual(s) who is knowledgeable about this request, who will conduct and manage this process, and has 1) appropriate written delegated procurement authority; and 2) completed mandatory training.
 (Type over "example" and delete cells not used.)

Name of Department Personnel	Division/Agency	Phone Number	e-mail address
Gail Kunimoto	DOH/SLD	453-6700	gail.kunimoto@doh.hawaii.gov

Department shall ensure adherence to applicable administrative and statutory requirements, including HAR Chapter 3-122, Subchapter 15, Cost or Price Data if required.

All requirements/approvals and internal controls for this expenditure is the responsibility of the department.

I certify that the information provided is to the best of my knowledge, true and correct.


 Department Head Signature

12/16/11
 Date

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For Chief Procurement Officer Use Only

11. Date Notice Posted: 12-20-11

Submit written objection to this notice to issue a sole source contract within seven calendar days or as otherwise allowed from date notice posted to:

Chief Procurement Officer
State of Hawaii
P.O. Box 119
Honolulu, HI 96810-0119

12. Chief Procurement Officer (CPO) Comments:

This approval is for the amount of \$20,000 and for the solicitation process only, HRS section 103D-310(c) and HAR section 3-122-112, shall apply (i.e. vendor is required to be compliant on the Hawaii Compliance Express) and award is required to be posted on the Awards Reporting System.

If there are any questions, please contact Donn Tsuruda-Kashiwabara at 586-0565.

Approved Disapproved No Action Required

Donn Tsuruda-Kashiwabara 1/25/2012
Chief Procurement Officer Signature Date

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6. Features: Describe in detail the unique features, characteristics, or capabilities of the goods, services, or construction. (continued from page 1)

The national algorithm for testing of oral fluids for HIV antibodies, in lieu of serum or plasma specimens, still require the use of a supplemental test. Orasure Technologies, Inc. is the manufacturer and sole distributor of the test kit. This is the only known FDA approved supplemental/confirmatory product for use with oral fluids.

The oral fluid collection devices manufactured by Orasure Technologies, Inc. is the only known FDA approved collection device for use with the oral fluid confirmatory western blot test kit.

7. Essential features: Describe in detail how the unique features, characteristics, or capabilities of the goods, services, or construction are essential for the department to accomplish its work. (continued from page 1)

The client reluctance level to the collection via venipuncture of a blood specimen, has been greatly reduced with the implementation of oral fluid testing. Other alternative body fluids when tested for HIV antibodies have not yielded sufficient sensitivity and specificity to be used.