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STATE PROCUREMENT OFFICE
NOTICE & REQUEST FOR SOLE SOURCE

STATE PROCUREMENT OFFICE
STATE OF HAWAII

1. TO: Chief Procurement Officer

2. FROM: Health/State Laboratories/Medical Microbiology Branch
Department/Division/Agency

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

3. Description of goods, services, or construction:
Human Immunodeficiency Virus Oral Fluid Test Kits & Oral Fluid Specimen Collection Devices

4. Vendor Name: OraSure Technologies, Inc. Address: 150 Webster Street Bethlehem, PA 18015	5. Price: $100,000
6. Term of Contract: (mm/dd/yyyy) From: CPO Approval To: 12 Months	7. Prior Sole Source Ref No. 09-020-J

8. Feature: The good, service, or construction has the following unique features, characteristics, or capabilities:
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 the specialized training for the collection of blood via venipuncture which requires specialized training.

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 distributer 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.

9. Essential features. How the unique features, characteristics, or capabilities are essential for the agency to accomplish its work: The use of alternative specimens for the presence or absence of HIV related antibodies, enables the control programs 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 an 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 colleciton beyond the normal boundaries, has enhanced the ability for the control program to extend testing into areas that have been previously inaccessible. 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.

11. Alternate source. The following other possible sources for the good, service, or construction were investigated but do not meet our needs because: OraSure Technologies, Inc. is the only known FDA approved manufacturer and supplier of oral fluid test 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.

12. **Direct any inquiries to:**	13 Phone Number:
Department: Health	453-6700
Contact Name/Title: Gail Y. Kunimoto, Chief, Medical Micro	Fax Number: 453-6716

Expenditure may be processed with a purchase order/p-Card: ☐ Yes ☐ No If no, a contract must be executed and funds certified.

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

14 ***I certify that the information provided above is to the best of my knowledge, true, correct and that the goods, services, or construction are available through only one source.***

Department Head Signature

DEC 2 2 2009

Date

Reserved for SPO Use Only

15 Date Notice Posted: 12/29/09

Submit written objections to this notice to issue a sole source contract within seven calendar days or as otherwise allowed from the above posted date to: Chief Procurement Officer
State Procurement Office
P.O. Box 119
Honolulu, Hawaii 96810-0119

16. Chief Procurement Officer's comments:

This approval is based on the department's representation that these manufacturer's kits and accessories are available from only this vendor. Sole source procurements in excess of $100,000 require cost or pricing data pursuant to subchapter 15, Chapter 3-122, HAR.

17.

☒ **APPROVED** ☐ **DISAPPROVED** ☐ **NO ACTION REQUIRED** James. Fujii 1/28/2010

Chief Procurement Officer Date

9. S.S. No. 10-028-B