



06 OCT -2 08:17

STATE PROCUREMENT OFFICE NOTICE & REQUEST FOR SOLE SOURCE

- 1 TO: Chief Procurement Officer
- 2 FROM: Health/State Laboratories/Medical Microbiology
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

4 Vendor Name: bioMerieux, Inc. (Formerly Organon Teknika)
Address: 100 Akzo Avenue
Durham, NC 27712

5 Price:
\$100,000

6. Term of Contract: From: 10/15/2006 To: 10/14/2007
(mm/dd/yyyy)

7. Prior Sole Source Ref No.
06-16-C

8. Feature: The good, service, or construction has the following unique features, characteristics, or capabilities: The test kits to be purchased are USFDA approved for the screening of oral fluid for antibodies to the Human Immunodeficiency Virus (HIV) Type 1. This agent has been identified as one of the causative agents of Acquired Immune Deficiency Syndrome (AIDS). The product is unique in that it enables testing of oral fluids for the presence of absence of antibodies for 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 counselling and specimen collection to be done by individuals who do not require the specialized training for the collection of blood via venipuncture. Venipuncture is considered a minor surgical procedure and therefore requires specialized training.

The national algorithm for testing of oral fluids, in lieu of serum or plasma specimens, still require the use of a supplemental test. At the current time, bioMerieux, Inc. (formerly Organon Teknika, Inc.) is the only supplier of FDA approved oral fluid test kits. The FDA has approved both the EIA and WB kits from bioMerieux, Inc. formerly Organon Teknika, Inc. The bioMerieux products are the only known FDA approved products for use with oral fluids.

Current equipment and instrumentation is proprietary to bioMerieux, Inc. and is not compatible with any other manufacturer's test kits and reagents.

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 Counselling 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 collection 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: bioMerieux, Inc. formerly Organon Teknika, Inc., is the only known FDA approved manufacturer and supplier of oral fluid test materials. National studies have indicated that the use of oral fluids yields better sensitivity and specificity for HIV antibodies, than other body fluids, such as urine.

12. Direct any inquiries to:
 Department: Health
 Contact Name/Title: Gail Y. Kunimoto/Chief, Medical Microbiology

13 Phone Number:
453-6700
 Fax Number:
453-6716

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

Agency shall ensure adherence to applicable administrative and statutory requirements.

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.

Gail Y. Kunimoto
 Department Head

SEP 29 2006

Date

Record for SPO Use Only

15 Date Notice Posted: 10/2/06

Submit written objections to this intent 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:

17.

APPROVED DISAPPROVED NO ACTION REQUIRED

Adrian S. Fisher
Chief Procurement Officer

10/9/06
Date