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STATE OF HAWAII REQUEST FOR SOLE SOURCE

STATE PROCUREMENT OFFICE
STATE OF HAWAII

TO: Chief Procurement Officer

FROM: Department of Health/State Laboratories Division/Medical Microbiology Branch

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

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| <p>Description of goods, services, or construction:</p> <p><u>Human Immunodeficiency Virus Oral Fluid Test Kits</u></p> |
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| <p>Name of Vendor: <u>bioMerieux, Inc</u> (Formerly <u>Organon Teknika, Inc</u>)</p> <p>Address: 100 Akzo Avenue Durham, NC 27712</p> | <p>Cost: <u>Seventy Thousand Dollars</u> <u>(\$70,000).</u></p> |
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| <p>Term of Contract: From: <u>October 15, 2004</u> To: <u>October 14, 2005</u></p> | <p>Prior Bid Exemption Reference No.(s): 04-13-J, 03-34-J, 02-24-J.</p> |
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| <p>The goods, services, or construction has the following unique features, characteristics, or capabilities:</p> <p>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). This product is unique in that it enables testing of oral fluids for the presence or 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.</p> <p>The national algorithm for testing of oral fluids, in lieu of serum or plasma specimens, still required 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 the oral fluid format.</p> |
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REQUEST FOR SOLE SOURCE (Cont)

How the unique features, characteristics, or capabilities are essential for the agency to accomplish its work:

The use of alternative specimens for testing 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 program to extend testing into areas that have been 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.

The following other possible sources for the goods, services, 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.

Direct questions to: GAIL Y. KUNIMOTO, Chief, Medical Microbiology Branch Phone: (808) 453-6700

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.

Linda Rosen MD MPH SEP 27 2004
Department/Agency Head Date

Title (If other than Department/Agency Head)

Chief Procurement Officer's Comments:

Please ensure adherence to applicable administrative and statutory requirements

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

Approved _____ Denied

Alan J. Taylor 10/6/04
Chief Procurement Officer Date