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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:

Description of goods, services, or construction:
Human Immunodeficiency Virus EIA Test Kits

Name of Vendor: **Bio-Rad Laboratories (Genetic Systems)**	Cost: **Ninety Thousand Dollars ($ 90,000).**
Address: 1000 Alfred Nobel Drive Hercules, CA 94547	

Term of Contract: From: **October 15, 2004** To: **October 14, 2005**	Prior Bid Exemption Reference No.(s) 04-12-J, 03-35-R, 02-22J, 01-21R, 00-14R, 99-24-J, 98-52-R, 97-53-J, 95-220-R, 94-588-J, 93-500-R, 92-351, 91-17.

The goods, services, or construction has the following unique features, characteristics, or capabilities:

The test kits to be purchased are USFDA approved for the screening of human serum or plasma for antibodies to the Human Immunodeficiency Virus (HIV), Type 1 and Type 2. These agents have been identified as the causative agents of Acquired Immune Deficiency Syndrome (AIDS). For many years, test kits were developed and marketed to detect HIV-1. Several years ago, with the discovery of a second HIV, newer test kits for this second virus were developed. Currently, test kits come in an individual format, in which each type of HIV can be tested separately, and a combination format, in which both agents can be tested for in one procedure. This product, from Bio-Rad Laboratories, who acquired the Sanofi Diagnostics Pasteur, is marketed by their Genetic Systems division, uses a peptide antigen. The use of this type of antigen is believed to yield sensitive results, without a large number of false positives.

The diagnostic algorithm, used in the nation's public health laboratories, for testing for HIV, requires the screening of all specimens by an Enzyme Immunoassay (EIA) procedure. Any initial screen positives, are repeated in duplicate, to rule out technician error, and if found positive, a supplemental test is performed. The use of the individual test format would require each specimen to be tested for each type and repeated if found positive. The use of the combination test, allows for the screening of both types of HIV and the differential identification can be performed by use of supplemental tests.

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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 licensure of the combination HIV-1 & HIV-2 test kits, made available a new generation of EIA test kits to laboratories. Currently blood banks are required to screen all units of blood for both these agents and many public health laboratories have developed this capability. The use of the combination test kits enables the Department to screen for both types of HIV. This product is made from viral peptides, which produce a high level of sensitivity, while the Abbott Laboratories product is a recombinant virus mixture, which has been shown to be extremely specific for HIV-1 and HIV-2. The use of both products will ensure the algorithm used by the Department, will be both sensitive and specific.

Bio-Rad Laboratories/Genetic Systems and Abbott Laboratories, at this time, manufacture the only USFDA approved products available in the Nation. Bio-Rad, through its acquisition of Sanofi Diagnostics Pasteur, is the current holder of the US patent on the HIV-2 virus. Currently pending legal suits to prevent the marketing of any HIV-2 type products, appears to be a major factor in the licensure of additional HIV combination products or any HIV-2 specific products.

The following other possible sources for the goods, services, or construction were investigated but do not meet our needs because:

The only other USFDA licensed product is produced by Abbott Laboratories, Inc. and a request for sole source is also being submitted for this product. This information was confirmed during the Association of Public Health Laboratories Conference on Human Retrovirus Testing on March 7-9, 2000.

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 Ako 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 X No ____. If no, a contract must be executed and funds certified.

X Approved ____ Denied

Chief Procurement Officer 10/6/04

Date

SPO Form-1 (Rev. 6/98)

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