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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 EIA Test Kits

4. Vendor Name: Abbott Laboratories Address: 100 Abbott Park Road Abbott Park, Illinois 60064-3500	5. Price: <u>\$100,000</u>
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6. Term of Contract: (mm/dd/yyyy) From: <u>CPO Approval</u> To: <u>12 Months</u>	7. Prior Sole Source Ref No. <u>07-022-J</u>
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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 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, tests kits were developed and marketed to detect HIV-1 only. 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 Abbott Laboratories is a combination test and uses a viral recombinant antigen. The use of this type of antigen is believed to yield highly specific results, with a reasonable level of sensitivity.

The diagnostic algorithm, used in most of the nation's public health laboratories, for testing for HIV, requires the screening of all specimens by and Enzyme Immunoassay (EIA) procedure. Any initial screen positive, is 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 for the screening of both types of HIV and the differential identification can be performed by the use of supplemental tests.

Current equipment and instrumentation is proprietary to Abbott Laboratories and is not compatible for use with other manufacturer's test kits.

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Human Immunodeficiency Virus EIA Test Kits

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11. Alternate source. The following other possible sources for the good, service, or construction were investigated but do not meet our needs because: (continued)

which utilizes a recombinant virus mixture and had demonstrated better specificity than the Bio-Rad Laboratories' test kit, was selected to be the stand-alone HIV-1/2 EIA test kit to be used for screening serum specimens for HIV antibody.

9. Essential features. 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 of 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. The Bio-Rad Laboratories, who acquired Genetic Systems, product, is made from viral peptides, which produces a high level of sensitivity, while the Abbott Laboratories product is a recombinant virus mixture, which has demonstrated to be extremely specific for both HIV-1 and HIV-2.

BioRad and Abbott Laboratories, at this time, manufacture the only USFDA approved products available in the Nation. BioRad, as part of the acquisition, currently is the holder of the US patent on the HIV-2 virus. There are current legal suits to prevent the marketing of any HIV-2 type products, appears to be a major factor in the non-licensure of additional HIV combination products or any HIV-2 specific products.

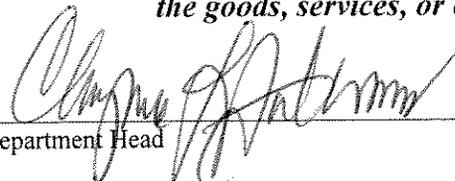
11. Alternate source. The following other possible sources for the good, service, or construction were investigated but do not meet our needs because: The only other USFDA licensed product is produced by Bio-Rad Laboratories, who acquired Sanofi Diagnostics Pasteur. The Bio-Rad Laboratories test kit utilizes viral peptides which had been demonstrated to be highly sensitive for both HIV-1 and HIV-2. Our laboratory maintained a dual serum screening algorithm for over ten years. When oral fluid testing for HIV became available, the STD Control Program found it cost prohibitive to maintain the dual testing algorithm for screening serum specimens. After review of ten years of our laboratory's comparative data, the Abbott Laboratories HIV-1/2 test kit, (see attached sheet)

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


 Department Head

OCT 11 2007
 Date

Reserved for SPO Use Only	
15 Date Notice Posted: <u>10/15/07</u>	
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: <p style="text-align: center;"> Chief Procurement Officer State Procurement Office P.O. Box 119 Honolulu, Hawaii 96810-0119 </p>	

16. Chief Procurement Officer's comments:

17.

APPROVED DISAPPROVED NO ACTION REQUIRED

Charles S. Fajal 10/22/07
Chief Procurement Officer Date