



11 07-5 2008

**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 & Accessories

4. Vendor Name: Abbott Laboratories Address: 100 Abbott Park Road Abbott Park, Illinois 60064-3500	5. Price: \$100,000
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6. Term of Contract: (mm/dd/yyyy) From: CPO Approval To: 12 Months	7. Prior Sole Source Ref No. 08-031J
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8. Feature: The good, service, or construction has the following unique features, characteristics, or capabilities: State Laboratories' equipment and instrumentation is proprietary to Abbott Laboratories. No other products are USFDA approved to be used with this equipment.

The test kits and accessories 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 an 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.

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. Bio-Rad Laboratories, who acquired the 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)

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

13 Phone Number:  
453-6700  
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.

OCT - 8 2008

Department Head Signature

Date

Reserved for SPO Use Only

15 Date Notice Posted: 10/10/08

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

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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.

16. Chief Procurement Officer's comments:

This approval is based on the DOH State Laboratory's representation that these are the only USFDA approved test kit with the level of required sensitivity, is essential for their work and available from only this vendor.

17.

APPROVED    DISAPPROVED    NO ACTION REQUIRED

*Oliver S. Fyfe*  
Chief Procurement Officer

*10/17/08*  
Date

## ACCESSORIES FOR ABBOTT LABORATORIES HIV-1/2 EIA

List No	Description	Product Category	Saleable Unit
01B07-01	PPC OPTICAL REF. SOLN	ACCESSORIES	EACH
05785-10	100T EIA ACCESSORIES	ACCESSORIES	EACH
05785-50	500 T EIA ACCESSORIES	ACCESSORIES	EACH
03A46-37	DIL TUBING FILTER(EA)	DISPOSABLES, SPARE PARTS	EACH
05577-25	ACCESSORY BLANK BEADS	ACCESSORIES	EACH
05785-05	10X20 EIA TUBE RAC	ACCESSORIES	EACH
05785-06	10X60 EIA TUBE RAC	ACCESSORIES	EACH
05785-07	40X20 EIA TUBE RAC	ACCESSORIES	EACH
05785-08	40X60 EIA TUBE RAC	ACCESSORIES	EACH
06155-01	MULTI BEAD DISPENSE BOX 1	DISPOSABLES, SPARE PARTS	EACH
06155-20	SINGLE BEAD DISPENS BOX 1	DISPOSABLES, SPARE PARTS	EACH
06171-05	10 X 20 RIA TUBE RACKS	ACCESSORIES	EACH
06172-24	OPD REAG PKG(100 TE 1	ACCESSORIES	EACH
06172-30	OPD REAG PKG (500 T 1 KIT	ACCESSORIES	EACH
06208-20	WATER CANNISTER(1-EACH)	ACCESSORIES	EACH
06208-21	WASTE CONTAINER(1-EACH)	ACCESSORIES	EACH
06208-22	WASTE CAP(1-EACH)	DISPOSABLES, SPARE PARTS	EACH
06208-23	H2O WASTE TUBING(1-EACH)	DISPOSABLES, SPARE PARTS	EACH
06208-24	H2O LEVEL CABLE(1-EACH)	DISPOSABLES, SPARE PARTS	EACH
06208-26	H2O/AIR FILTER(1-EACH)	DISPOSABLES, SPARE PARTS	EACH
06208-31	COMMANDER REMOTE OUTLET TUBE	DISPOSABLES, SPARE PARTS	EACH
06208-32	COMMANDER DISPENSER, 50 UL	DISPOSABLES, SPARE PARTS	EACH
06208-33	COMMANDER DISPENSER, 0.1 ML	DISPOSABLES, SPARE PARTS	EACH
06208-34	COMMANDER DISPENSER, 0.175 ML	DISPOSABLES, SPARE PARTS	EACH
06208-35	COMMANDER DISPENSER, 0.2 ML	DISPOSABLES, SPARE PARTS	EACH
06208-36	COMMANDER DISPENSER 0.3 ML	DISPOSABLES, SPARE PARTS	EACH
06208-38	20 WELL COMMANDER TRAY COVERS	DISPOSABLES, SPARE PARTS	EACH
06208-39	60 WELL COMMANDER TRAY COVERS	DISPOSABLES, SPARE PARTS	EACH
06208-40	FUSES-5 AMP(PKG 5)	DISPOSABLES, SPARE PARTS	EACH
06208-41	FUSES-10 AMP(PKG 5)	DISPOSABLES, SPARE PARTS	EACH
06208-42	COMMANDER RGT BLANK BEADS	DISPOSABLES, SPARE PARTS	EACH
06208-57	GASKETS, MANIFOLD(5 EACH)	DISPOSABLES, SPARE PARTS	EACH
06208-58	PPC MANIFOLD ASSY(EACH)	DISPOSABLES, SPARE PARTS	EACH
06208-74	ALLEN DRIVER(1 EACH)	DISPOSABLES, SPARE PARTS	EACH
06208-75	COMMANDER LAMP(1 EACH)	DISPOSABLES, SPARE PARTS	EACH
06208-84	DISPENSER 150 UL, COMMANDER	DISPOSABLES, SPARE PARTS	EACH
06262-06	BARCODE LABEL/BOX(EACH)	DISPOSABLES, SPARE PARTS	EACH
06262-07	BARCODE LABEL/TRAY(EACH)	DISPOSABLES, SPARE PARTS	EACH
07184-24	ASSAY TUBES-D (100) BAG 1	DISPOSABLES, SPARE PARTS	EACH
07186-06	HC1 DISPENSER(TRI-C 1 DISPENSE	DISPOSABLES, SPARE PARTS	EACH
07186-11	5 ML OPD DILUENT DI 1 DISPENSE	DISPOSABLES, SPARE PARTS	EACH
07186-12	FORCEPS FOR EIA ACC 1 BOX OF 2	DISPOSABLES, SPARE PARTS	EACH
07186-19	0.5ML DISPENSER(TRI 1 BOX	DISPOSABLES, SPARE PARTS	EACH
07186-20	1.0 ML DISPENSER 1 BOX	DISPOSABLES, SPARE PARTS	EACH
07186-38	0.4ML DISPENSER TRI-CONTINENT	DISPOSABLES, SPARE PARTS	EACH
07212-30	1 N SULFURIC ACID BOX(5BTL)	ACCESSORIES	EACH
07803-15	10X20 WELL REAC	ACCESSORIES	EACH
07803-16	10X60 WELL REAC	ACCESSORIES	EACH
07803-17	40X20 WELL REAC	ACCESSORIES	EACH
07803-18	40X60 WELL REAC	ACCESSORIES	EACH