



PROCUREMENT OFFICE
STATE OF HAWAII

STATE PROCUREMENT OFFICE NOTICE OF AND REQUEST FOR EXEMPTION FROM CHAPTER 103D, HRS

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

Department/Division/Agency

Pursuant to §103D-102(b)(4), HRS, and Chapter 3-120, HAR, the Department requests a procurement exemption to purchase the following:

3. Description of goods, services or construction:
Human Immunodeficiency Virus EIA Test Kits & Accessories

4. Name of Vendor: Abbott Laboratories
Address: 100 Abbott Park Road
Abbott Park, Illinois 60064-3500

5. Price:
\$100,000

6. Term of Contract: From: CPO Approval To: June 2011

7. Prior Exemption Ref. No.
10-043D

8. Explanation describing how procurement by competitive means is either not practicable or not advantageous to the State: State Laboratories' equipment and instrumentation is proprietary to Abbott Laboratories. No other products are USFDA approved to be used with this equipment.

Abbott Laboratories and Bio-Rad Laboratories manufacture the only USFDA approved products to detect HIV-1 and HIV-2 antibodies in serum available by enzyme immunoassay in the Nation. Our laboratory has used the Abbott Laboratories' HIV-1/2 EIA to screen serum specimens for the presence of HIV-1 and HIV-2 antibodies for over 14 years. The Abbott Laboratories' assay is a combination test and uses a viral recombinant antigen which

9. Details of the process or procedures to be followed in selecting the vendor to ensure maximum fair and open competition as practicable:
We already use both of the USFDA approved products for screening different types of patient specimens by enzyme immunoassay so there is already fair and open competition. These are the only 2 USFDA approved EIA tests for detection of HIV-1 and HIV-1 antibodies and the products serve as primary or contingency products for the SLD.

10. A description of the agency's internal controls and approval requirements for the exempted procurement:
The approval process within the Communicable Disease Division (CDD) for purchases >\$5,000 requires CDD Chief or designee approval. The STD Program Coordinator is responsible for administering/monitoring the contract.

4084

8. Explanation describing how procurement by competitive means is either not practicable or not advantageous to the State.

is believed to yield highly specific results, with a reasonable level of sensitivity. Bio-Rad Laboratories manufactures and distributes the Genetics Systems HIV-1/2 + O EIA assay, which is a combination test utilizing recombinant and synthetic peptides which produces a high level of sensitivity without a large number of false positives, while the Abbott Laboratories product is a recombinant virus mixture, which has demonstrated to be extremely specific for both HIV-1 and HIV-2 in our laboratory.

The Abbott Laboratories' product is used primarily to screen serum specimens while the Bio-Rad product will be used to screen oral fluid specimens for the presence of HIV-1 and HIV-2 antibodies (See Request for Exemption from Chapter 103D, HRS, P.E. No. 10-044-K). Since the Bio-Rad product is also USFDA approved for use with serum specimens, our laboratory has already verified the product to screen serum specimens as a contingency in the event the Abbott Laboratories' product becomes unavailable to ensure continuous testing for HIV antibody for the department's disease control program.

Procurement by competitive means is not practicable or not advantageous to the State at this time. Abbott Laboratories has announced retirement of the Abbott EIA HIVAB HIV-1/HIV-2 (rDNA) EIA in March 2011. See attached letter dated July 2010 from Abbott Laboratories. We are requesting approval of this Exemption from 103D for the Abbott Laboratories HIV-1/2 EIA product and accessories to allow the SLD sufficient time to use up current inventory of product and to migrate to the new 4th generation assay, Abbott ARCHTECT HIV AG/AB COMBO TEST, which will be submitted as a Sole Source Request as the only USFDA approved 4th generation HIV antigen/antibody combination assay.

REQUEST FOR EXEMPTION FROM CHAPTER 103D, HRS (Cont.)

12. A list of agency personnel, by position, who will be involved in the approval process and administration of the contract:		
Name	Position	Involvement in Process
Venie Lee	Acting STD Program Coordinator	<input checked="" type="checkbox"/> Approval <input checked="" type="checkbox"/> Administration
Kevin Nomura	STD/AIDS Branch PHAO	<input checked="" type="checkbox"/> Approval <input type="checkbox"/> Administration
Peter Whitar	STD/AIDS Branch Chief	<input checked="" type="checkbox"/> Approval <input type="checkbox"/> Administration
Dr. Glenn Wasserman	Communicable Disease Div. Chief	<input checked="" type="checkbox"/> Approval <input type="checkbox"/> Administration
		<input type="checkbox"/> Approval <input type="checkbox"/> Administration
		<input type="checkbox"/> Approval <input type="checkbox"/> Administration

13. Direct inquiries to: Department: Health
 Contact Name: Gail Y. Kunimoto
 Phone Number: 453-6700
 Fax Number: 453-6716

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 and correct.*


 Department Head

NOV 12 2010
 Date

Reserved for SPO Use Only

15. Date Notice Posted 11/16/2010

The Chief Procurement Officer is in the process of reviewing this request for exemption from Chapter 103D, HRS. Submit written objections to this notice to issue an exemption from Chapter 103D, HRS, 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

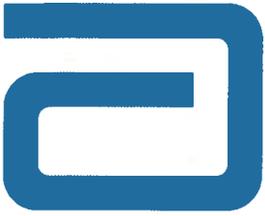
Chief Procurement Officer's comments:

From information provided by the contact person, Ms. Gail Kunimoto, she has identified Ms. Venie Lee and Mr. Peter Whitar as also being participants in this request. Although no written delegated procurement authority is required for a *Request for Exemption from Chapter 103D, HRS*, it is noted that Mr. Whitar has not taken the appropriate required mandatory procurement training. It is also noted that none of the above individuals have any written delegated procurement authority. As a reminder, Ms. Kunimoto, Ms. Lee and Mr. Whitar shall not participate in any procurement activities until they have received both written delegated procurement authority and have completed the appropriate mandatory procurement training requirements for the applicable procurement method, pursuant to Procurement Delegation No. 2008-01 and Procurement Circular No. 2008-05.

This approval is conditioned on the above and based on the department's representation that although there is competition in the marketplace for HIV Virus EIA test kits and accessories, only Abbott test kits and accessories can be used in the Abbott equipment that is used by the department. This award is required to be posted on the Awards Reporting System.

16. APPROVED DISAPPROVED NO ACTION REQUIRED


 Chief Procurement Officer Date 12/1/2010



Abbott Diagnostics
100 Abbott Park Road
D-MKTG/AP6C-5
Abbott Park, IL 60064
Tel: (877) 4ABBOTT

July 2010

Dear Abbott Infectious Disease Customer,

Abbott Diagnostics is committed to providing newer, more automated tests for your laboratory. Over the past several years, Abbott has launched innovative automated infectious disease assays and platforms. Our infectious disease heritage includes the first test for hepatitis B in 1971, the first antibody test for HIV in 1985, and the first high-volume fully-automated infectious disease testing platform, ABBOTT PRISM, in 2006.

In order to effectively manage our product portfolio, we must focus our resources on our automated platforms. This letter serves to announce the upcoming retirement of Abbott EIA HIVAB™ HIV-1/ HIV-2 (rDNA) EIA (LN 3A77). The product's final lot expiration dating will be March 2011.

Abbott provides excellent replacement products for HIV testing. ARCHITECT HIV Combo (2P36) was FDA approved on June 18, 2010 and is expected to begin shipping in September 2010. PRISM HIV O Plus (LN 3L68) launched in October 2009 and is currently available.

Managing the life cycle of our products will enable us to better meet your expectations in terms of product availability and product support. Your Abbott sales representative will contact you to discuss a transition plan and alternative Abbott infectious disease assays. In the meantime, should you have any questions, please contact your Abbott Customer Service representative at 1-877-4ABBOTT.



Sincerely,

John Coulter
Vice President,
U.S. Commercial Operations
Abbott Diagnostics Division

Put science on your side.

ID-10-28471 v1.0, page 1 of 1

 **Abbott**
A Promise for Life