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STATE PROCUREMENT OFFICE
NOTICE & REQUEST FOR SOLE SOURCE

STATE PROCUREMENT OFFICE
STATE OF HAWAII

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

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

3. Description of goods, services, or construction:
ARCHITECT HIV Ag/Ab Combo Test and accessories by Abbott Laboratories

4. Vendor Name: Abbott Laboratories
Address: 100 Abbott Park Road
Abbott Park, Illinois 60064-3500
5. Price: \$100,000

6. Term of Contract: From: CPO APPROVAL To: 12 MONTHS
7. Prior Sole Source Ref No.

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.
This assay is the only U.S.F.D.A. approved 4th Generation assay available for simultaneous qualitative detection of human immunodeficiency virus (HIV) p24 antigen and antibodies to HIV type 1 (HIV-1 group M and group O) and/or type 2 (HIV-2) in human serum and plasma (EDTA and heparin). The ARCHITECT HIV Ag/Ab Combo assay is intended to be used as an aid in the diagnosis of HIV-1/HIV-2 infection, including acute or primary HIV-1 infection. This assay may be used as an aid in the diagnosis of HIV-1/HIV-2 infection in pediatric subjects (i.e. children as young as two years of age) and in pregnant women.
Acquired immunodeficiency syndrome (AIDS) is caused by two types of human immunodeficiency viruses, collectively designated as HIV. HIV is transmitted by sexual contact, exposure to blood or blood products, and prenatal or perinatal infection of a fetus or newborn. Antibodies against HIV are nearly always detected in AIDS patients and HIV-infected asymptomatic individuals.
Phylogenetic analysis classifies HIV-1 into groups M (major), N (non-M, non-O), O (outlier) and P. HIV-1 group M is composed of genetic subtypes (A-D, F-H, J, and K) and circulating recombinant forms (CRFs) and has spread throughout the world to cause the global AIDS pandemic. Geographic distribution and regional predominance of HIV-1 subtypes and CRFs vary. HIV-2 type 2 (HIV-2) is similar to HIV-1 in its structural morphology, genomic organization, cell tropism, in vitro cytopathogenicity, transmission routes, and ability to cause AIDS. HIV-2 is endemic to West Africa, (see Attached Sheet)

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REQUEST FOR SOLE SOURCE

Laboratory Test Kits and Accessories for Detection of HIV p24 Antigen and Antibodies to HIV types 1 and 2 using Chemiluminescent Microparticle Immunoassay

March 29, 2011

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8. The good, service, or construction has the following unique features, characteristics or capabilities: (continued)

but HIV-2 infections have been identified in North America and Europe at a low frequency when compared to HIV-1.

Early after infection with HIV-1, but prior to seroconversion, HIV-1 core protein, p24 antigen may be detected in HIV-1-infected individuals. ARCHITECT HIV Ag/Ab Combo uses anti-HIV-1 p24 antibodies as reagents to detect HIV-1 p24 antigen, thereby decreasing the window period and improving early detection of HIV infection.

The key immunogenic protein for serodetection of HIV is the viral transmembrane protein (TMP). Antibodies against the TMP are consistently among the first to appear during seroconversion of HIV-infected individuals and remains relatively strong throughout the asymptomatic and symptomatic stages of HIV infection.

ARCHITECT HIV Ag/Ab Combo detects antibodies to HIV-1 groups M and O, and HIV-2 through the use of five recombinant proteins and two synthetic peptides derived from native TMP sequences of groups M and O, and HIV-2.

REQUEST FOR SOLE SOURCE (Cont.)

Submit in Triplicate

9. Essential features. How the unique features, characteristics, or capabilities are essential for the agency to accomplish its work: The ARCHITECT HIV Ag/Ab Combo assay is a chemiluminescent microparticle immunoassay (CMIA) for the simultaneous qualitative detection of human immunodeficiency virus (HIV) p24 antigen and antibodies to HIV type 1 (HIV-1 group M and group O) and/or type 2 (HIV-2) in human serum and plasma (EDTA and heparin).

The use of the ARCHITECT HIV Ag/Ab Combo assay will detect HIV-1 p24 antigen and allow the STD Control Program to decrease the window period thereby improve early detection of HIV infection. Repeatedly reactive specimens will be investigated further with supplemental confirmatory HIV-specific tests including immunoblots, antigen tests, and HIV nucleic acid tests. Supplemental testing of repeatedly reactive specimens obtained from individuals with HIV infection usually confirms the presence of HIV antibodies, HIV antigen, or HIV nucleic acid. A full differential diagnostic work-up for the diagnosis of AIDS and AIDS-related conditions includes an examination of the patient's immune status and a clinical history.

11. Alternate source. The following other possible sources for the good, service, or construction were investigated but do not meet our needs because: There are none.

12. Direct any inquiries to:

Department: Health

Contact Name/Title: Gail Y. Kunimoto, Chief, Medical Microbiology

13 Phone Number:

453-6700

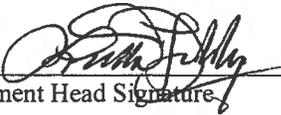
Fax Number:

453-6716

Expenditure may be processed with a purchase order/pCard: 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.*



Department Head Signature

4/7/11
Date

Reserved for CPO Use Only

15 Date Notice Posted: 4/7/2011

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

16. Chief Procurement Officer's comments:

Approval is based on the department's representation that Abbott Laboratories is the only vendor that sells the ARCHITECT HIV Ag/Ab Combo Test kits and accessories that are essential for the agency to perform their work. Sole source contracts in excess of \$100,000 require cost or pricing data pursuant to HAR chapter 3-122, subchapter 15. This approval is for the solicitation process only, HRS section 103D-310(c) and HAR section 3-122-112, shall apply and award is required to be posted on the Awards Reporting System.

17. APPROVED DISAPPROVED NO ACTION REQUIRED


Chief Procurement Officer

4/18/2011
Date

Abbott Laboratories Inc.
Contracting & Pricing
100 Abbott Park Rd.
D-943 CP1-4
Abbott Park, IL 60064-6095

800 323 9100
847 938 7539



3/15/2011

State of Hawaii Department of Health
2725 Waimano Home Road, 2nd Floor
Pearl City, HI 96782

ATTN: Gail Y. Kunimoto, Chief
Medical Microbiology Branch

Dear Ms. Kunimoto,

This letter is to inform you that the recently approved Architect HIV Ag/Ab Combo assay (02P36) is approved to be run on an Architect Immunoassay system only. Please consult the current package insert for a complete description of the operational and technical information regarding the use of this assay. Both the Architect Immunoassay systems and the HIV Combo assay are manufactured by Abbott Diagnostics and Abbott Diagnostics is the only authorized seller of these products to the State of Hawaii Department of Health. Abbott Diagnostics has a direct sales force and would directly contract with the State of Hawaii Department of Health. No other companies are authorized to sell or contract for the above stated products.

Please feel free to contact your local Abbott Sales representative Thomas Woo or consult www.abbottdiagnostics.com for additional information.

Best regards,

A handwritten signature in blue ink that reads "Joseph G. Patt".

Joseph G. Patt
Area Manager