



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

12 MAY -4 A8:54

STATE PROCUREMENT OFFICE  
STATE OF HAWAII

TO: Chief Procurement Officer

FROM: HEALTH/STATE LABORATORIES DIVISION  
*Name of Requesting Department*

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

1. Describe the goods, services or construction:  
ARCHITECT HIV Ag/Ab Combo Test and Accessories by Abbott Laboratories

2. Vendor/Contractor/Service Provider:	Abbott Laboratories	3. Amount of Request:	
		\$ 100,000	
4. Term of Contract From:	CPO APPROVAL	To:	12 MONTHS
		5. Prior SPO-007, Procurement Exemption (PE):	

6. Explain in detail, why it is not practicable or not advantageous for the department to procure by competitive means:  
The State Laboratories' equipment and instrumentation is proprietary to Abbott Laboratories. No other products are USFDA approved to be used with this equipment.  
The ARCHITECT HIV Ag/Ab Combo Test by Abbott Laboratories was the first 4th generation assay approved by the U.S.F.D.A. (See S.S. No. 11-059-B) and its use was validated and implemented into our laboratory's HIV testing algorithm. Since the implementation of the ARCHITECT HIV Ag/Ab Combo Test, the Bio-Rad GS HIV Combo Ag/Ab EIA test was U.S.F.D.A. approved for use with plasma/serum on 7/22/2011. Both assays do simultaneous detection of HIV p24 antigen and antibodies to HIV-1 (Groups M and O) and HIV-2 in human serum or plasma. The ARCHITECT HIV Ag/A Combo assay by Abbott Laboratories uses chemiluminescent microparticle immunoassay (CMIA) technology while the the GS HIV Combo Ag/Ab EIA by Bio-Rad uses the older enzyme immunoassay technology. A reactive result on either assay does not distinguish between the detection of HIV-1 p24 antigen, HIV-1 antibody, or HIV-2 antibody.  
Please see the attached page 3

7. Explain in detail, the process that will be or was utilized in selecting the vendor/contractor/service provider:  
The State Laboratories Division uses the 4th generation ARCHITECT HIV Ag/Ab Combo assay to do the initial screening on serum/plasma specimens for the detection of HIV p24 antigen and antibodies to HIV -1 (M and O) and HIV-2 and was validated for use under S.S. No. 11-059-B. The SLD equipment and instrumentation is proprietary to Abbott Laboratories. No other products are USFDA approved to be used with this equipment.  
Our laboratory currently uses the 3rd generation Genetic Systems HIV-1/2 + O EIA test kits for screening oral fluid specimens for HIV-1/2 antibodies and as contingency in the event the Abbot product is not available although we do not have the capability to detect HIV-1 antigen. Similarly, Bio-Rad's equipment and software is proprietary to Bio-Rad and is not USFDA approved to be used with any other products.  
Both manufacturers' HIV products are currently being used in our laboratory.

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6. Explain in detail, why it is not practicable or not advantageous for the department to procure by competitive means:

It is not practicable or advantageous for the department to procure by competitive means because our laboratory's HIV testing algorithm uses the ARCHITECT HIV Ag/Ab Combo assay to screen human serum and plasma specimens. Specimens that are initially reactive in the ARCHITECT HIV Ag/Ab Combo assay will be retested in duplicate by the protocol. Repeat reactivity is highly predictive of the presence of HIV-1 p24 antigen and/or HIV-1/HIV-2 antibodies. The assay does not distinguish between the detection of HIV-1 p24 antigen, HIV-1 antibody, or HIV-2 antibody. A repeatedly reactive specimen should be investigated further with supplemental confirmatory HIV-specific tests, such as western blots or IFA tests, antigen tests, and HIV nucleic 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.

Early after infection with HIV-1, but prior to seroconversion, HIV-1 core antigen may be detected in HIV-1-infected individuals. The ARCHITECT HIV Ag/Ab Combo uses anti-HIV-1 p24 antibodies as reagents to detect HIV-1 p24 antigen, decreasing the window period and improving early detection of HIV infection. Improving early detection of HIV infection will enable disease control measures to be implemented sooner and identification of patients at risk. In the ARCHITECT HIV Ag/Ab Combo assay the key immunogenic protein for serodetection of HIV infection is the viral transmembrane protein (TMP). Antibodies to TMP are consistently among the first to appear during seroconversion of HIV-infected individuals and remain relatively strong throughout the asymptomatic and symptomatic stages of infection. The 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 HIV -1 groups M and O, and HIV-2.

Our laboratory is also currently using the 3<sup>rd</sup> generation Bio-Rad HIV-1/2 + O EIA Test Kit for oral fluid specimens (See PE No. 12-082K). The 3<sup>rd</sup> generation EIA test is used for contingency in the event the Abbott product is unavailable and the Bio-Rad Western Blot is used as contingency for the Maxim Biomedical HIV-1 Western Blot Test. The 3<sup>rd</sup> generation Bio-Rad HIV-1/2 + O EIA Test Kit can also now be used to differentiate between the HIV-1 and HIV-2 antibodies.

It is more advantageous to use the ARCHITECT HIV Ag/Ab Combo by Abbott Laboratories than the GS HIV Combo Ag/Ab EIA because the total running time of the Abbott assay is 30 minutes vs. 2 hours for the Bio-Rad assay. In addition, the Bio-Rad assay is more labor intensive because it is a manual assay vs. the ARCHITECT platform which is an automated system.

PE 12-102K

8. Identify the primary individual(s) who is knowledgeable about this request, who will conduct and manage this process, and has 1) completed mandatory training; and 2) who may contact for follow up inquiry, if any.  
 (Type over "example" and delete cells not used.)

Name of Department Personnel	Division/Agency	Phone Number	e-mail address
Gail Y. Kunimoto	SLD/Medical Micro	453-6700	gail.kunimoto@doh.hawaii.gov

**All requirements/approvals and internal controls for this expenditure is the responsibility of the department. I certify that the information provided above is, to the best of my knowledge, true and correct.**

  
 \_\_\_\_\_  
 Department Head Signature

\_\_\_\_\_  
 Date 4/20/10

**For Chief Procurement Officer Use Only**

Date Notice Posted: 5/4/12

Submit written objection to this notice to issue an exempt contract within seven calendar days or as otherwise allowed from date notice posted to:

[state.procurement.office@hawaii.gov](mailto:state.procurement.office@hawaii.gov)

Chief Procurement Officer (CPO) Comments:

Request is disapproved as vendor is not compliant with HRS §103D-310(c) and HAR §3-122-112 (i.e. vendor must be compliant on the Hawaii Compliance Express [HCE]). Upon verification of vendor compliance, department may attach a memo to this request, along with a copy of HCE certificate requesting CPO approval.

If there are any questions, please contact Kevin Takaesu at 586-0568, or [kevin.s.takaesu@hawaii.gov](mailto:kevin.s.takaesu@hawaii.gov).

Approved     
  Disapproved     
  No Action Required

  
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 Chief Procurement Officer Signature

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 Date 6/6/2012