



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

12 FEB 24 A9:45

STATE PROCUREMENT OFFICE  
STATE OF HAWAII

TO: Chief Procurement Officer

FROM: Health ISLD  
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:  
HIV EIA Test Kits & Western Blot Test Kits

2. Vendor/Contractor/Service Provider:	Bio-Rad Laboratories, Inc.	3. Amount of Request:
		\$ 75,000
4. Term of Contract From:	3/11/2012 To: 3/10/2013	5. Prior SPO-007, Procurement Exemption (PE): 11-030-K

6. Explain in detail, why it is not practicable or not advantageous for the department to procure by competitive means:  
State Laboratories' equipment, instrumentation, and software is proprietary to Bio-Rad Laboratories. No other products are USFDA approved to be used with this equipment.  
The tests to be purchased are USFDA approved for screening of human serum, plasma, and cadaveric serum for antibodies to the Human Immunodeficiency Virus (HIV) Types 1 (Groups M and O) and/or 2 (HIV-1/HIV-2). These agents have been identified as the causative agents of Acquired Immunodeficiency Virus Syndrome (AIDS). This product, from Bio-Rad Laboratories, who acquired Sanofi Diagnostics Pasteur, is marketed by their Genetic Systems division, uses recombinant and synthetic peptide antigens. The use of this type of antigen is believed to yield sensitive results, without a large number of false positives.  
This product is intended to be used to primarily screen oral fluid specimens by enzyme immunoassay in our laboratory. Discontinuation by bioMerieux, Inc., manufacturer of the only FDA approved oral fluid HIV-1 EIA screening test at the end of 2007 forced public health laboratories to validate testing oral fluid specimens using a serum-based EIA (See Attached Sheet)

7. Explain in detail, the process that will be or was utilized in selecting the vendor/contractor/service provider:  
We already use both products for different types of patient specimens so there is already a fair and open competition. These are the only 2 USFDA approved EIA tests for HIV-1 and HIV-2 and the products serve as primary or contingency products for the State Laboratories Division.  
Bio-Rad Laboratories manufactures and is the sole distributor of the Genetic Systems HIV-1/2 + O EIA test kits. Our laboratory selected to validate this product for use with oral fluid specimens for detection of HIV-1/2 antibodies based on current available information. Full validation of this product is to be used with oral fluid specimens was a huge undertaking for this laboratory in order to meet very stringent criteria requirements by federal law for validation of an off-label product. Our laboratory completed the full validations/comparison study using the Bio-Rad HIV-1/2 + O EIA Test Kit with oral fluid specimens. (See Attached Sheet)

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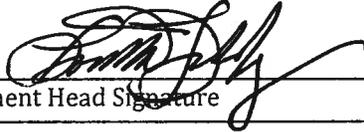
8. Identify the primary individual(s) who is knowledgeable about this request, who will conduct and manage this process, and has 1) completed mandatory training; and 2) who may contact for follow up inquiry, if any.  
 (Type over "example" and delete cells not used.)

Name of Department Personnel	Division/Agency	Phone Number	e-mail address
Gail Kunimoto	SLD/MMB	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



2/23/12

**For Chief Procurement Officer Use Only**

Date Notice Posted:

2/27/12

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:

Approval is granted from 03/11/12 to 03/10/13 and is based on the department's representation that Bio-Rad will be used as a contingency plan should Maxim products become unavailable and is the only other manufacturer that produces USFDA Western Blot Test Kits. This approval is for the solicitation process only, HRS section 103D-310(c) and HAR section 3-122-112, shall apply (i.e. vendor is required to be compliant on the Hawaii Compliance Express) and award is required to be posted on the Awards Reporting System.

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

  
 Chief Procurement Officer Signature

Date

REQUEST FOR EXEMPTION FROM CHAPTER 103D

Human Immunodeficiency Virus EIA Test Kits and Western Blot Test Kits

February 6, 2012

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

in order to maintain testing of oral fluid specimens, which has shown to yield better sensitivity and specificity for HIV antibodies than that of other alternative body fluids to serum.

Avioq, Inc. has received FDA approval for use of their HIV-1 EIA with serum and oral fluid specimens in October 2009, however, it is only approved to detect HIV-1 antibody and not HIV-2 antibody and their product cannot be used to screen blood donors.

In addition, there are currently only two USFDA approved supplementary or confirmatory tests by western blot for use on HIV-1 serum screen test reactive specimens. The USFDA approved western blot test kits are the Cambridge Biotech HIV-1 Western Blot Test Kit manufactured and distributed by Maxim Biomedical, Inc. and the Bio-Rad HIV-1 Western Blot Test Kit. Procurement by competitive means for the Bio-Rad HIV-1 Western Blot Test Kits is not practicable or advantageous to the State because our laboratory already performs the Cambridge Biotech HIV-1 Western Blot Test as the primary supplementary/confirmatory test kit for HIV-1 antibody screen reactive specimens.

We are requesting to have the Bio-Rad HIV-1 Western Blot Test available for contingency use, as may be needed if the test of its only competitor, Cambridge Biotech HIV-1 Western Blot, becomes unavailable or has quality assurance issues.

7. Explain in detail, the process that will be or was utilized in selecting the vendor/contractor/or provider:

Our laboratory also utilizes the ARCHITECT HIV Ag/Ab Combo Assay which is the only USFDA 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). (See SS11-059-B) 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.

PE12-082K