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STATE PROCUREMENT OFFICE  
STATE OF HAWAII

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**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:  
HIV EIA Test Kits & Western Blot Test Kits

4. Name of Vendor: Bio-Rad Laboratories, Inc.  
Address: 1000 Alfred Nobel Drive  
Hercules, CA 94547

5. Price:  
\$175,000

6. Term of Contract: From: CPO Approval To: 12 Months

7. Prior Exemption Ref. No.  
10-044K

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 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, (See Attached Sheet)

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 products for different types of patient specimens so there already is a fair and open competition. These are the only 2 FDA 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 has selected to validate this product for use with oral fluid specimens for detection of HIV-1/2 antibodies based on current available information. (See Attached Sheet)

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 of the contract.

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

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 including the Florida Bureau of Laboratories and the San Francisco Public Health Laboratory to validate testing oral fluid specimens using a serum-based EIA 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 announced that they 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.

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 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 the only competitor, Cambridge Biotech HIV-1 Western Blot, becomes unavailable or has quality assurance issues.

9. Details of process or procedures to be followed in selecting the vendor to ensure maximum fair and open competition as practicable.

Full validation of this product to be used with oral fluid specimens was a huge undertaking for this laboratory in order to meet very stringent criteria requirements by

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federal law for validation of an off-label product. Our laboratory completed the full validation/comparison study using the Bio-Rad HIV-1/2 + O EIA Test Kit with oral fluid specimens and not the short term interim proposal by the Association of Public Health Laboratories approved by the Centers for Medicare and Medicaid Services (CMS).

The only other USFDA licensed product to screen for HIV-1/2 antibodies in serum by enzyme immunoassay is manufactured by Abbott Laboratories which our laboratory is currently performing. Our laboratory has had over 14 years of documented data on the performance of this HIV-1/2 EIA assay. The current equipment and instrumentation is proprietary to Abbott Laboratories and is not compatible or approved for use with any other manufacturer's reagent test kits. (See P.E. No. 10-043-D).

