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

- 1. TO: Chief Procurement Officer
- 2. FROM: Health/State Laboratories Division/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 Test Kits
 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~~ 10/17/09 *GA*

7. Prior Exemption Ref. No.
 08-039-J

8. Explanation describing how procurement by competitive means is either not practicable or not advantageous to the State:
 Procurement by competitive means is not practicable or advantageous to the State.
 The State Laboratories Division (SLD) needs to use an HIV-1/2 test approved for testing blood for oral fluid specimens because the oral fluid test manufacturer stopped making the tests ("off-label" use). Only Bio-Rad Laboratories is seeking FDA approval for inclusion of oral fluid for use with its blood test, so it is the only product known to us with a chance of eventual federal approval.

The test kits to be purchased are USFDA approved for the 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 (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 SLD.

Bio-Rad Laboratories manufactures and is the sole distributor of the Genetic Systems HIV-1/2 + O EIA test kits, Bio-Rad Laboratories is the only known manufacturer that has declared its intention to submit for USFDA approval their product for use to screen oral fluid specimens. Our laboratory has selected to validate this product for use with oral fluid specimens 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.

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

(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 has forced public health laboratories 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 other alternative body fluids to serum such as serum.

There are currently 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 Kit 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 screen reactive specimens.

We seek 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.

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

Validation of this product is 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 is currently performing a full validation/comparison study using the Bio-Rad HIV-1/2 + O EIA Test Kit with oral fluid specimens and not the

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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 secured a sole source approval for the Abbott Laboratories HIV-1/2 EIA Test for use with serum specimens based on over 10 years of comparative laboratory data. The current equipment and instrumentation is proprietary to Abbott Laboratories and is not compatible with any other manufacturer's reagent test kits.

