

**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: Upon CPO Approval To: 12 Months

7. Prior Exemption Ref. No.

8. Explanation describing how procurement by competitive means is either not practicable nor advantageous to the State:
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 (HIV-1/HIV-2). These agents have been identified as the causative agents of Acquired Immunodeficiency Syndrome (AIDS). This product, from Bio-Rad Laboratories, who acquired the Sanofi Diagnostics Pasteur, is marketed by their Genetic Systems division uses a recombinant and synthetic peptide antigen. 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 (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:

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 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.

Validation of this product is a huge undertaking for this laboratory in order to meet very stringent criteria (See Attached Sheet)

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

immunoassay in our laboratory. The sudden discontinuation by bioMerieux, Inc. manufacturer of the only FDA approved oral fluid HIV-1 EIA screening test kit by the end of the year has forced public health laboratories to validate testing oral fluid specimens using a serum-based EIA in order to maintain testing of oral fluids which has shown to yield better sensitivity and specificity for HIV antibodies than other alternative body fluids to serum such as urine.

Procurement by competitive means is not practicable or advantageous to the State. No other manufacturer of any USFDA approved serum based EIA test kit approved for detection of HIV-1/2 antibodies has declared to Orasure Technologies, manufacturer of the Orasure collection devices and the only USFDA approved western blot kit used for confirmation of oral fluid reactive screen specimens, of their intention to submit clinical data for approval of their serum based test kits for use with oral fluid specimens. Bio-Rad Laboratories is the only manufacturer that has done so and has approached the USFDA on the length of the approval process which may take as long as 2 - 3 years for approval.

Other public health laboratories in Florida, Ventura County in California and the Centers for Disease Control and Prevention (CDC) have already validated the use of the Genetic Systems HIV-1/2 + O EIA test kit for use with oral fluid specimens. San Francisco's Public Health Laboratory is also planning on validating the use of this test kit for screening oral fluid specimens this fall. The number of public health laboratories validating this test kit allows sharing of valuable laboratory data.

There are currently two USFDA approved confirmatory test kits 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 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 confirmatory test kit for HIV-1 screen reactive specimens.

We are looking to validate the Bio-Rad HIV-1 Western Blot Test Kit as an alternative confirmatory test.

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

REQUEST FOR EXEMPTION FROM CHAPTER 103D, HRS
Human Immunodeficiency Virus EIA Test Kits and Western Blot Test Kits
November 6, 2007
Page 3

requirements by federal law for validation of an off label product. Our laboratory is proposing to perform a 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 and approved by the Centers for Medicare and Medicaid Services (CMS).

The only other USFDA licensed product to screen for HIV-1/2 antibodies for 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 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.

REQUEST FOR EXEMPTION FROM CHAPTER 103D, HRS (Cont.)

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 orders >\$5,000 requires CDD Chief or designee approval. The STD Program Coordinator is responsible for administration/monitoring of the contract.

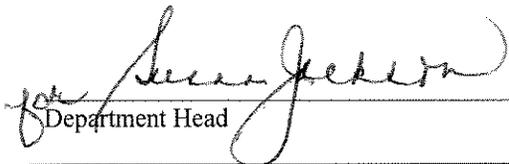
12. A list of agency personnel, by position, who will be involved in the approval process and administration of the contract:

Name	Position	Involvement in Process	
Roy Ohye	STD Program Coordinator	<input checked="" type="checkbox"/> Approval	<input checked="" type="checkbox"/> Administration
Kevin Nomura	STD/AIDS Branch PHAO	<input checked="" type="checkbox"/> Approval	<input type="checkbox"/> Administration
Peter Whiticar	STD/AIDS Branch Chief	<input checked="" type="checkbox"/> Approval	<input type="checkbox"/> Administration
Dr. Glenn Wasserman	Communicable Disease Div Chief	<input checked="" type="checkbox"/> Approval	<input type="checkbox"/> Administration
		<input type="checkbox"/> Approval	<input type="checkbox"/> Administration
		<input type="checkbox"/> Approval	<input type="checkbox"/> Administration

13. Direct inquiries to: Department: Health
 Contact Name: Gail Y. Kunimoto
 Phone Number: 453-6700
 Fax Number: 453-6716

Agency shall ensure adherence to applicable administrative and statutory requirements

14. *I certify that the information provided above is, to the best of my knowledge, true and correct.*


 Department Head

11/09/07
 Date

Reserved for SPO Use Only

15. Date Notice Posted 11/14/07

The Chief Procurement Officer is in the process of reviewing this request for exemption from Chapter 103D, HRS. Submit written objections to this notice to issue an exemption from Chapter 103D, HRS, 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

REQUEST FOR EXEMPTION FROM CHAPTER 103D, HRS (Cont.)

Chief Procurement Officer's comments:

This approval is for the solicitation process only, HRS section 103D-310(c) and HAR section 3-122-112, shall apply.

16.



APPROVED



DISAPPROVED



NO ACTION REQUIRED

Ann S. Fujita 11/23/07
Chief Procurement Officer Date



October 19, 2007

Judith Yost, MA, MT(ASCP)
Director, Division of Laboratory Services
Centers for Medicare and Medicaid Services
7500 Security Blvd
Baltimore, MD 21244

Dear Judy,

As you know, APHL members remain concerned about the discontinuation of the bioMérieux Vironostika Oral Fluid and Serum HIV-1 EIA test kits and its' effects on public health testing. We are writing to seek assistance and guidance from CMS to prevent laboratories from suffering a complete loss of oral fluid testing capabilities, which would result in a devastating public health situation.

APHL would like to propose a solution to address the urgent public health need for HIV screening capacity for oral fluid specimens in public health laboratories. Please review the attached information. If you have any questions or need additional information, please contact Mr. Tony Tran, HIV, STD, TB Program Manager (anthony.tran@aphl.org) at 240-485-2783 or Scott Becker, Executive Director (scott.becker@aphl.org) or via phone at 240-485-2747.

On behalf of the public health laboratories, any assistance CMS could provide, to address this urgent situation, would be greatly appreciated. We look forward to working with CMS on a solution to this public health problem.

Sincerely,

A handwritten signature in black ink that reads "William J. Becker". The signature is written in a cursive style with a large, prominent initial "W".

William J. Becker, DO, MPH
APHL President, 2007-2008

A handwritten signature in black ink that reads "Michael A. Pentella". The signature is written in a cursive style with a large, prominent initial "M".

Michael Pentella, PhD
APHL/CDC HIV Steering Committee Chair

2018 Georgia Avenue
Suite 700
Silver Spring, MD
20910-3493

240.485.2745 phone
202.496.2700 fax

www.aphl.org

APHL Proposal to Address the Urgent Need for HIV Screening Capacity for Oral Fluid Specimens in Public Health Laboratories

Situation: Discontinuation of bioMérieux Vironostika Oral Fluid and Serum HIV-1 EIA test kits

In October 2005 the Centers for Medicare and Medicaid Services (CMS) approved a short term proposal allowing public health laboratories to complete a small scale validation to use the Vironostika serum HIV-1 enzyme immunoassay (EIA) to test oral fluid specimens. bioMérieux has ceased production and sale of the oral fluid and serum assays, thus the proposal is no longer helpful for oral fluid testing. There are no other FDA-approved oral fluid assays available on the market for laboratory testing. Currently, many public health laboratories have a very limited supply of oral fluid kits. Oral fluid (OF) specimens collected via the OraSure collection device can only be stored for up to 6 weeks frozen.

Due to the lack of an FDA approved oral fluid assay and an increasing number of oral fluid specimens for HIV testing, public health laboratories must have an option to test oral fluid specimens. APHL is seeking the assistance and guidance of CMS so that public health laboratories have a method to continue oral fluid testing for HIV and service is not interrupted. APHL is requesting CMS's timely approval of this proposal. Without the approval of this proposal many laboratories may lose the ability to test specimens for HIV, which could result in disastrous consequences for public health. Any assistance CMS can provide to address this immediate need is greatly appreciated. *There is an urgent need to find other testing capabilities to screen OF specimens for HIV infection as they continue to be submitted to public health laboratories.*

Background

The bioMérieux Vironostika oral fluid HIV-1 EIA was previously the only screening assay on the market for use with oral fluid. Over the past several years the oral fluid product has been on sustained back-order repeatedly, leaving public health laboratories scrambling for alternative testing options. In December 2006, bioMérieux announced their plans to discontinue the production and sale of the Vironostika oral fluid and serum HIV-1 test kits from the United States domestic market. The last oral fluid kits were shipped to laboratories in June 2007.

Ten public health laboratories reported that they performed a validation study using the serum-based Bio-Rad HIV-1/2 plus O EIA to test oral fluids. These laboratories sent their validation study data to APHL for compilation (see below). Of these ten laboratories, eight performed their validation in parallel on the oral fluid Vironostika HIV-1 EIA, and the remaining two performed their validation in comparison to the serum Vironostika HIV-1 EIA (previously validated for use with oral fluids). Data were also collected from a Centers for Disease Control and Prevention (CDC) validation study and compiled into the tables below.

The primary procedural difference between the Bio-Rad HIV-1/2 plus O serum EIA and the Vironostika HIV-1 oral fluid EIA is the dilution factor. Each assay requires the same amount of specimen (75µl) but is diluted to different concentrations. The OF bioMérieux kit specimens are diluted to a ratio of 1:2 and the Bio-Rad serum kit specimens are diluted to a ratio of 3:4. All

laboratories indicated that there were no procedural modifications and all instructions were followed according to each assay's package insert.

Comparison data

Comparisons among the two EIA test kits with follow-up testing performed on the OraSure HIV-1 Western blot (WB) show favorable results. The specificity of the Bio-Rad serum kit tested on OF is slightly higher than that of the bioMérieux OF kit, while the opposite was true regarding sensitivity. Both differences are statistically insignificant ($p>0.05$).

The following pooled data encompasses *all eleven* laboratories (ten public health laboratories and the CDC) that performed a validation study. This includes validations performed on the Vironostika HIV-1 serum EIA and the Vironostika HIV-1 oral fluid EIA:

Total number of oral fluid samples = 6071
 Total number of True Positives=1290
 Total number of True Negatives=4781

Comparison of EIA Methods to Western blot:

	Vironostika HIV-1 EIA (serum and OF kits)	Bio-Rad HIV-1/2 plus O
False Positives	42	0
Specificity	99.1%	100%
False Negatives	1	10
Sensitivity	99.9%	99.2%

Comparison of EIA Methods on Oral Fluid Specimens:

Bio-Rad HIV-1/2 plus O EIA vs. Vironostika HIV-1 serum and OF EIAs

Bio-Rad HIV-1/2 plus O EIA	Vironostika HIV-1 Serum and OF EIA		
	Reactive	Nonreactive	Total
Reactive	1279	1	1280
Nonreactive	52*	4739	4791
Total	1331	4740	6071

Note: Table includes all ten public health laboratories and CDC validation data
 * 42 of 52 specimens did not confirm positive.

The following pooled data encompasses the *nine* laboratories (eight public health laboratories and the CDC) that performed a validation study utilizing the bioMérieux Vironostika HIV-1 OF EIA as the original assay. Laboratories that performed a validation utilizing the Vironostika HIV-1 serum EIA as the original assay are excluded from this data set:

Total number of oral fluid samples = 3791
 Total number of True Positives=1227
 Total number of True Negatives=2564

Comparison of EIA Methods to Western blot:

	Vironostika HIV-1 EIA (OF Only)	Bio-Rad HIV-1/2 plus O
False Positives	8	0
Specificity	99.7%	100%
False Negatives	1	10
Sensitivity	99.9%	99.2%

**Comparison of EIA Methods on Oral Fluid Specimens:
Bio-Rad HIV-1/2 plus O EIA vs. Vironostika HIV-1 OF EIA**

		Vironostika HIV-1 OF EIA		
Bio-Rad HIV-1/2 plus O EIA		Reactive	Nonreactive	Total
	Reactive	1216	1	1217
	Nonreactive	18*	2556	2574
	Total	1234	2557	3791

Note: Table includes eight public health laboratories and CDC validation data
* 8 of 18 did not confirm positive.

Proposal for short term resolution: Allow public health laboratories to utilize the Bio-Rad HIV-1/2 plus O serum based screening assay to test oral fluid specimens based on the data provided. Allow for this use until another EIA is FDA approved for use with oral fluid specimens.

Since oral fluid kits are no longer being produced and the last available kits will expire on November 19, 2007, APHL is requesting that public health laboratories that have not already validated a serum assay for use with oral fluid specimens, switch to an HIV serum screening assay to test oral fluid. On the basis of the composite comparison data shown above, APHL is proposing that laboratories that have not already done so, switch oral fluid screening to the Bio-Rad HIV-1/2 plus O EIA. This option has been thoroughly discussed with the APHL/CDC HIV Steering Committee and was deemed as one of a few viable options for public health laboratories to pursue during this national emergency.

Methodology

If supplies of remaining oral fluid Vironostika HIV-1 EIA kits are sufficient, laboratories that have not already validated the use of OF with a serum kit, will perform a comparison of at least 20 oral fluid specimens on each kit that will include at least 5-10 positive specimens and 10-15 negative specimens. The results must confirm that the site can obtain a sensitivity and specificity equivalent to what was shown with the composite data above. APHL requests that these laboratories be given a temporary exception under CLIA for this minimum comparison to allow for the continued testing of oral fluid specimens to meet the public health demand until another EIA screening assay receives FDA approval for use with oral fluid specimens. At that time, laboratories that have not performed comprehensive on-site comparison studies and wish to continue using serum kits for OF testing will need to perform more thorough studies for long term usage of the serum assay.

Date: October 25, 2007

To: Anthony Tran, MPH, MT (ASCP)
HIV, STD, TB Program Manager, APHL

From: Judith Yost, MA, MT (ASCP)
Director, Division of Laboratory Services, CMS /s/

Subject: APHL HIV Oral Fluid Test Proposal

CMS has received and reviewed the information that you provided on October 19, 2007 and we have conferred with CDC and FDA to ensure that we had a complete set of facts.

Based on that information, we will allow the public health laboratories to utilize this test to fill a gap in the marketplace on a temporary basis, under the following conditions.

- Laboratories in which the study was not conducted must perform a reasonable validation/comparison study of approximately 20 samples, prior to reporting patient results, to ensure that they can duplicate the data and results in the original study in their laboratory.
- High complexity personnel qualifications and responsibilities apply since the test is modified.
- The modified serum test being utilized for oral fluid may only be used until an FDA-approved/cleared oral fluid test becomes available. The public health laboratories must then discontinue the use of the modified serum test for oral fluid and begin using the new FDA approved test.
- We recommend that, in the circumstances when a high risk individual tests negative with the oral fluid screening test and there is an indication of infection, the public health laboratories will consider drawing a serum sample for further testing.
- All other applicable CLIA requirements must be met.

We congratulate APHL and the public health laboratories for their extra efforts in assuring that this testing is available in the interim.

If you have any questions about this memo, please don't hesitate to contact me at: 410-786-3407 or Judith.yost@cms.hhs.gov.