



Received by
State Procurement Office
09/06/2016

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

TO: Chief Procurement Officer

FROM: Health/SLD
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 and/or services:

Respiratory Viral Panel (RVP) Kits

2. Vendor/Contractor/Service Provider: Clinical Micro Sensors, Inc. dba Genmark Diagnostics 3. Amount of Request:

\$ 60,000

4. Term of Contract From: 1/1/2017 To: 12/31/2017 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:

It is not practicable or advantageous for the department to procure by competitive means for this product. The Genmark Respiratory Viral Panel (RVP) offers comprehensive detection of 14 respiratory virus types and subtypes including Influenza A, Influenza A H1, Influenza H3, Influenza A 2009 H1N1, Influenza B, Respiratory Syncytial Viruses (RSV) A and B, Parainfluenza Virus Types 1, 2, and 3, Human Metapneumovirus (hMPV), Human Rhinovirus (HRV), Adenovirus B/E, and Adenovirus C. The manufacturer claims to be the only respiratory kit to detect the Influenza A 2009 H1N1 subtype when compared with the other respiratory viral panels including but not limited to Luminex and the BioFire FilmArray assays. The CDC provides an Influenza PCR assay available only to public health laboratories that will differentiate and detect influenza viruses which is currently being used in-house as a stand alone influenza assay.

The Genmark RVP Assay utilizing Genmark's eSensor technology is based on the principles of competitive DNA hybridization and electrochemical detection. The eSensor technology is highly specific for the target biomarker and is not based on fluorescent or optical detection. See the Attached Sheet.

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

The Biological Response Section (BRS) of the Laboratory Preparedness and Response Program currently performs the Luminex RVP assay for epidemiological surveillance of detecting other viral respiratory pathogens for the ELC grant. The manufacturer has notified the BRS that the RVP will be discontinued at the end of the year. The manufacturer has another RVP product available but would involve upgrade to a new instrument and software. The RVP testing function will be transitioned to the Virology Section in January 2017. The Virology Section has evaluated this product and have found it to provide an excellent correlation with the current Luminex product. We will re-examine this product selection when additional RVP products become available. Another manufacturer, Hologic, has announced that they have submitted an RVP product to FDA for approval for use with the PANTHER System, which we currently have in-house to perform CT/GC testing by NAAT.

8. Identify the primary responsible staff person(s) conducting and managing this procurement. (Appropriate delegated procurement authority and completion of mandatory training required).

*Point of contact (Place asterisk after name of person to contact for additional information).

Name	Division/Agency	Phone Number	e-mail address
Gail Kunimoto	DOH/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.*

Virginia Brewer
Department Head Signature

SEP - 6 2016
Date

For Chief Procurement Officer Use Only

Date Notice Posted: 9/09/2016

Inquiries about this request shall be directed to the contact named in No. 8. 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

Chief Procurement Officer (CPO) Comments:

This request is disapproved. It does not meet the requirements for a procurement exemption as there are other vendors that provide similar RVP products. In addition, these vendors may provide a reagent rental program comparable to GenMark Diagnostics if given the opportunity to submit a bid. The Department shall use the appropriate method of procurement to solicit the goods/services being requested.

If there are any questions, please contact Kevin Takaesu at 586-0568 or kevin.s.takaesu@hawaii.gov.

Approved

Disapproved

No Action Required

Kevin Takaesu
for Chief Procurement Officer Signature

9/29/16
Date

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

As a result, diagnostic tests are less prone to sample contamination risk and does not require time-consuming washing and preparations steps. The Genmark eSensor technology does not require a large space footprint when compared to the BioFire Assay which would require equipment acquisition.

Genmark Diagnostics is the sole distributor of these test kits. See attached letter.

GenMark DX

GenMark Diagnostics
14000 E. Harvard Ave.
Denver, CO 80231

Main: 303.751.1000
Direct: 303.751.1000
Fax: 303.751.1000
www.genmarkdx.com

5/19/2016

Gail Kunimoto
Chief, Medical Microbiology Branch
Hawaii Department of Public Health
2725 Waimano Home Road
Pearl City, HI 96782

Dear Gail Kunimoto:

GenMark Diagnostics Inc. is the manufacturer of the eSensor XT-8 instrument (Part #s RM002038, RM002068, RM002069) and eSensor assay cartridges, including the eSensor Respiratory Viral Panel Assay (part #s MT005008 and part# MT005102).

GenMark Diagnostics is the sole supplier for the Assays mentioned above. GenMark has partnered with an authorized distributor for XT-8 instrumentation only that can be supplied to federal, state, and municipal government laboratories. The XT-8 instrument may only be procured from GenMark or such authorized distributor.

GenMark prides itself on the quality of our products and service and we are the only organization that provides routine maintenance and repair services for the eSensor XT-8 instrument, in accordance with the terms of our Maintenance and Support Agreement. GenMark technicians are the only personnel who have access to proprietary service tools and calibration specifications in the US necessary to perform maintenance and repair on the XT-8 platforms. In addition, GenMark employs a direct team of Technical Support Scientists who are available for both assay and instrument troubleshooting.

Please feel free to contact me if you have any questions of the content of this letter or our products.

Sincerely,



Michael Gleeson
Senior Vice President, North American Commercial Operations
GenMark Diagnostics