



STATE PROCUREMENT OFFICE
NOTICE & REQUEST FOR SOLE SOURCE

TO: Chief Procurement Officer
FROM: DOH/State Laboratories/Medical Microbiology Branch
Name of Requesting Department

Pursuant to HRS §103D-306 and HAR chapter 3-122, Subchapter 9, the Department requests sole source approval to purchase the following:

1. Describe the goods, services, or construction to be procured. E TEST STRIPS AND API TEST STRIPS AND ACCESSORIES

2. Vendor/Contractor/Service Provider Name: BIOMERIEUX, INC.	3. Amount of Request: \$30,000.00
4. Term of contract (shall not exceed 12 months), if applicable: From: 4/25/2016 To: 4/24/2017	5. Prior SPO-001, Sole Source (SS) No.: 15-047SK

6. Describe in detail the following: a. The unique features, characteristics, or capabilities of the goods, service or construction. E TEST is a well established method for antimicrobial resistance testing in microbiology laboratories. E TEST consists of a predefined gradient of antibiotic concentrations on a plastic strip and is used to determine the Minimum Inhibitory Concentration (MIC) of antibiotics, antifungal agents and antimycobacterial agents. Quantitative MIC data is now a prerequisite for the management of critical infections, including sepsis, especially among critical care patients. Etest for antimicrobial resistance testing is particularly valuable in situations where on-scale MICs are needed for treatment decisions. Etest is recognized as a cost-effect tool for generating MICs across 15 dilutions. It can also be used in a macromethod format to optimize resistance detection. Over 100 antibiotics are now available in the product range for testing of aerobic bacteria and fastidious organisms such as gonococci, menngococci, pneumococci, haemophilus, (see attached sheet) b. How the unique features, characteristics or capabilities of the goods, service or construction are essential for the department The SLD was recently selected as one of eight national laboratories to participate in the GC ETEST REPRODUCIBILITY PROJECT administered by the Association of Public Health Laboratories (APHL). This project required the use of selected ETEST antibiotic strips on GC isolates submitted from the CDC. The CDC analyzed the data from the selected laboratories with excellent correlation. In addition, the Hawaii DOH also has the distinction of identifying the first two highly resistant gonococcal (GC) isolates to Azithromycin in the United States using Etest strips. The Biomerieux API identification system are test strips for the identification of Gram positive and Gram negative bacteria and yeast. The kits include strips that contain up to 20 biochemical tests. This feature is advantageous to our laboratory since the only alternative is to produce the 20 biochemical tests in-house which is both labor and time consuming. The SLD is a reference laboratory where bacterial isolates are sent for confirmation and identification. The various API test strips are used in conjunction with other biochemical tests as well as other serological and molecular methodologies (see attached
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7. Describe the efforts and results in determining that this is the only vendor/contractor/service provider who can provide the goods, services or construction.

See the attached documentation by the manufacturer/sole source provider of the Etest and API Test Strips, Reagents and accessories.

8. Alternate source. Describe the other possible sources for the goods, services, or construction that were investigated but did not meet the department's needs.

There are none.

9. 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	SLD/MMB	453-6700	<i>gail.kunimoto@doh.hawaii.gov</i>

Department shall ensure adherence to applicable administrative and statutory requirements, including HAR chapter 3-122, Subchapter 15, Cost or Pricing Data if required.

*All requirements/approvals and internal controls for this expenditure is the responsibility of the department.
I certify that the information provided is to the best of my knowledge, true and correct.*



Department Head Signature

FEB 26 2016

Date

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6. Describe in detail the following:

- a. The unique features, characteristics, or capabilities of the goods, services, or construction.(continued)

H. pylori, anaerobes, fungi and mycobacteria.

Etest provides Minimum Inhibitory Concentrations (MICs) for slow-growing and fastidious organisms such as gonococci that have unique growth requirements and cannot be tested by automated methods; Antibiotic Susceptibility Testing (AST) and resistance mechanism detection; testing robust aerobes, anaerobes, pneumococci, gonococci, meningococci, and fastidious organisms such as the HACEK group, Bordetella and Francisella; and detects phenotypic resistance.

The API® Test Strips are a well-established method for manual identification of microorganisms to the species level. Biomerieux's API identification products are test kits for identification of Gram positive and Gram negative bacteria and yeast. The system which offers a large and robust database is now accessible through the Internet-based APIweb™. The API strips give accurate identifications based on extensive databases and are standardized, easy-to-use test systems. The kits include strips that contain up to 20 miniature biochemical tests. All are quick, safe and easy to perform. The API Test Strips have a long shelf life and the laboratory is able to keep the test kits on hand. The APIweb is a software product containing all of the API databases for a reliable automated interpretation of API strip results.

- b. How the unique features, characteristics, or capabilities of the goods, services or construction are essential for the department (continued)

to make a definitive identification. These additional biochemical tests and methodologies are often too cost prohibitive for community clinical laboratories to perform. In addition, our laboratory is required to confirm the presence of various reportable bacteria included in HAR Title 11, Chapter 156 and the use of the API test strips have proven to be beneficial for many of these identifications.

For Chief Procurement Officer Use Only

Date Notice Posted: 03/01/2016

Submit written objection to this notice to issue a sole source contract within seven calendar days or as otherwise allowed from date notice posted to:

state.procurement.office@hawaii.gov

Chief Procurement Officer (CPO) Comments:

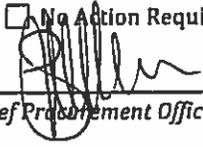
Approval is granted for the period from 4/25/2016 to 4/24/2017 and is based on the department's representation that the Etest strips and the API test strips and accessories may only be purchased through Biomerieux, Inc. This approval is for the solicitation process only, HRS section 103D-310(c) and HAR section 3-122-112, shall apply (i.e. vendor is required to provide proof of compliance and may use the Hawaii Compliance Express) and the award is required to be posted on the Awards Reporting System. Copies of the HCE certificate and the awards posting are required to be documented in the procurement/contract file.

If there are any questions, please contact Stacey Kauleinamoku at 586-0571, or stacey.l.kauleinamoku@hawaii.gov.

Approved

Disapproved

No Action Required


Chief Procurement Officer Signature

3/19/16
Date