



07 FEB 28 P 1:05

STATE PROCUREMENT OFFICE NOTICE & REQUEST FOR SOLE SOURCE

- 1. TO: Chief Procurement Officer
- 2. FROM: Health/State Laboratories/Medical Microbiology
Department/Division/Agency

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

3. Description of goods, services, or construction:
(Laboratory Test Kits based on nucleic acid amplification procedures, target capture, and dual kinetic assay)

4. Vendor Name: GEN-PROBE, INC Address: 10210 Genetic Center Drive San Diego, California 92121-4362	5. Price: <u>\$300,000Est</u>
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6. Term of Contract: (mm/dd/yyyy) From: 3/1/07 ^{upon CPD approval} To: 2/28/08	7. Prior Sole Source Ref No. <u>06-044J</u>
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8. Feature: The good, service, or construction has the following unique features, characteristics, or capabilities: The test kits are designed to provide laboratory evidence of infection by microbial agents. The analytical method used in these test kits are based on a concept termed target capture to yield the analyte to be amplified. The amplification procedure increases the sensitivity, which is the ability of the assay to detect small amounts of the agent in the specimen. The concept of target capture, decreases the possibility of the amplification of an incorrect genetic material, which could lead to false positive findings.

Genetic material, such as DNA and RNA are unique to each species of microbial agents, These kits are specifically prepared segments of genetic materials linked to a chemical marker. Genetic material recovered from patient's specimens are prepared and allowed to react with these prepared segments. In the event that the prepared segments and the isolate's segments match, a binding occurs and through the use of a chemical reaction, a positive signal is sent to an instrument. In the event of a non match, no binding occurs and no chemical reaction occurs and a negative response is sent to the instrument. A positive signal is an indication of the identity of the organism. This procedure, since it uses the specific genetic material from known organisms and the binding phenomenon is unique for each species, produces highly accurate results. The use of the procedure is rapid and accurate.

This method is highly sensitive and specific. Due to the use of instrumentation and known reagents based on genetic material, the results are objective and highly accurate. The use of these kits allow for the rapid diagnoses of patients, however, without the ability to recover the organism. the formulation of these (continued on attached sheet)

9. Essential features. How the unique features, characteristics, or capabilities are essential for the agency to accomplish its work: Our current system allows us to use both individual nucleic acid assays and a dual kinetic design which allows for the simultaneous detection and identification of both Chlamydia trachomatis and Neisseria gonorrhoeae. All other FDA approved test kits require the performance of individual assays or detection procedures to achieve this result. These products are also approved for a longer specimen transport and storage period of time than the other products. All other known products require testing within 7 days of collection and these products allow the specimen to be tested, if stored properly, up to 60 days after collection. This property is an essential consideration, especially with the transport times from neighbor island facilities. The availability of a urine transport system, which will reduce the possibility of cross contamination, also provides the ability to test non invasive specimens. This will allow for the testing of patients from areas where the collection of specimens requiring invasive procedures is not available. These products are (continued on attached sheet)

11. Alternate source. The following other possible sources for the good, service, or construction were investigated but do not meet our needs because: No other manufacturer is able to provide this technology. Individual nucleic acid assays from other manufacturers and Gen-Probe have been reviewed and found to be too labor intensive and costly to implement. The specimen transport times for all other FDA approved products are limited to 7 days from date of collection. The current equipment is only compatible with reagent test kits using the Gen-Probe Aptima technology.

<p>12. Direct any inquiries to: Department: <u>Health</u> Contact Name/Title: <u>Gail Y. Kunimoto/Chief, Medical Microbiology</u></p>	<p>13 Phone Number: <u>453-6700</u> Fax Number: <u>453-6716</u></p>
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Expenditure may be processed with a purchase order: Yes No If no, a contract must be executed and funds certified.

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, correct and that the goods, services, or construction are available through only one source.*

Gail Y. Kunimoto
 Department Head

FEB 27 2007

Date

Reserved for SPO Use Only

15 Date Notice Posted: 3/2/07

Submit written objections to this intent to issue a sole source contract 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

16. Chief Procurement Officer's comments:

This approval is based on the DOH's representation that only this manufacturer's test kits offers the necessary individual nucleic acid assays and dual kinetic design necessary for their purposes and is compatible with their current instrumentation.

17.

APPROVED DISAPPROVED NO ACTION REQUIRED

Alvin S. Taylor
Chief Procurement Officer

3/9/07
Date

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8. The good, service, or construction has the following unique features, characteristics or capabilities: (continued)

products allows the laboratory the flexibility of using an individual assay for selected low incidence populations for *Chlamydia trachomatis* screening only and for the use of a dual kinetic assay for selected higher disease incidence populations. The dual kinetic assay allows for the detection of both *Chlamydia trachomatis* and *Neisseria gonorrhoeae* one test run. This is accomplished through the use of dissimilar kinetic detection systems. This dual system reduces the amount of time compared with the requirement of conducting assay methods specific for these agents. In essence, this one procedure allows the detection or absence and identification of both agents, without additional testing. Since the test is based on unique genetic properties of the organisms, no additional confirmatory testing is required.

~~No other test kits are compatible with our instrumentation.~~

9. Essential Features. How the unique features, characteristics, or capabilities are essential for the agency to accomplish its work. (continued)

also the only known FDA approved products that allow for testing of patient and physician collected vaginal specimens in addition to female endocervical and male urethral specimens. This will allow the Department's control program to evaluate the incidence of disease in geographic areas that have not been tested.