



11 APR -7 P2:10

STATE PROCUREMENT OFFICE
STATE OF HAWAII

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

3. Description of goods, services, or construction:
 Laboratory Test Kits & Accessories 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: \$500,000
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6. Term of Contract: (mm/dd/yyyy) From: <u>CPO APPROVAL</u> To: <u>12 MONTHS</u>	7. Prior Sole Source Ref No. <u>10-035K</u>
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8. Feature: The good, service, or construction has the following unique features, characteristics, or capabilities: Our equipment is proprietary to Gen-Probe. No other test kits are compatible with our instrumentation. The test kits are designed to provide laboratory evidence of infection by microbial agents. The analytical method used in these 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 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 the 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 an instrument. A positive signal is an indication of the identity of the organism. The procedure, since it uses the specific genetic material from known organisms and the binding phenomenon is unique for each specimes, produces highly accurate results. The use of the procedure is rapid and accurate.

(continued on attached sheet)

4932

REQUEST FOR SOLE SOURCE (Cont.)

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 simulataneous 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 allows the specimen to be tested, if stored properly, up to 60 days after collection. (Stability studies performed by the manufacturer have shown that female swab specimens and male and female urine specimens may be frozen up to 12 months, while male urethral swabs may be stored for up to 6 months from date of collection.) This property is an essential consideration, especially with the transport times from neighbor island facilities and other jurisdictions requiring longer transport times.

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 and up to 30 days for some type of specimens from date of collection. The current equipment is only compatible with reagent test kits using the Gen-Probe Aptima technology.

12. Direct any inquiries to:
Department: Health
Contact Name/Title: Gail Y. Kunimoto, Chief, Medical Microbiology

13 Phone Number:
453-6700
Fax Number:
453-6716

Expenditure may be processed with a purchase order/pCard: Yes No
If no, a contract must be executed and funds certified.

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

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.*


Department Head Signature

4/7/11
Date

Reserved for CPO Use Only

15 Date Notice Posted: 4/7/11

Submit written objections to this notice 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

REQUEST FOR SOLE SOURCE (Cont.)

16. Chief Procurement Officer's comments:

Approval is based on the department's representation that Gen-Probe Inc. test kits and accessories are proprietary to the State's equipment. Sole source contracts in excess of \$100,000 require cost or pricing data pursuant to HAR chapter 3-122, subchapter 15. This approval is for the solicitation process only, HRS section 103D-310(c) and HAR section 3-122-112, shall apply and award is required to be posted on the Awards Reporting System.

17. APPROVED DISAPPROVED NO ACTION REQUIRED

David J. Taylor 6/30/2011
Chief Procurement Officer Date

REQUEST FOR SOLE SOURCE

Laboratory Test Kits Based on Nucleic Acid Amplification, Target Capture and Dual Kinetic Assay

March 24, 2011

Page 2

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

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

The dual kinetic assay allows for the detection of both *Chlamydia trachomatis* and *Neisseria gonorrhoeae* on 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.

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

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 also the only known FDA approved products that allow for testing of patient and physician collected vaginal specimens, female and male urine 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.

Monday, March 21, 2011

State of Hawaii
State Laboratory Division
Department of Health
ATTN: Gail Kunimoto
2725 Waimano Home Road, 2nd Floor
Pearl City, Hawaii 96782

Dear Gail,

Gen-Probe Incorporated would like to verify that we are the sole source for the following products, which utilize proprietary technology, including technology contained in but not limited to one or more of the following patents:

Cat. #1032 APTIMA COMBO 2[®] Assay for detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* (100 test kit) U.S. Patent No. 4,851,330; 4,950,613; 5,030,557; 5,185,439; 5,283,174; 5,288,611; 5,399,491; 5,437,990; 5,480,784; 5,512,445; 5,514,551; 5,541,308; 5,556,771; 5,567,587; 5,585,481; 5,601,984; 5,612,200; 5,614,387; 5,639,604; 5,641,631; 5,656,207; 5,656,744; 5,658,737; 5,688,645; 5,693,468; 5,696,251; 5,714,324; 5,723,597; 5,756,011; 5,756,709; 5,827,656; 5,834,254; 5,840,488; 5,840,873; 5,888,779; 5,948,899; 6,004,745; 6,031,091; 6,090,591; 6,110,678; 6,150,517; 6,245,519; 6,280,952; 6,410,276; 6,414,152; RE37,891; 6,512,105; 6,534,273; Australian Patent No. 605743; 613989; 616646; 618965; 619223; 626319; 630076; 633474; 650622; 651371; 699590; 708543; 710884; 726821; 737017; 738708; 776290; Canadian Patent No. 1,215,904; 1,278,987; 1,314,009; 1,319,336; 1,333,396; 1,339,303; 1,339,871; 1,339,872; 1,340,843; 2,020,958; 2,201,595; and other international counterparts.

Cat. #1088 APTIMA[®] CT Assay for detection of *Chlamydia trachomatis* (100 test kit) U.S. Patent No. 4,851,330; 4,946,958; 4,950,613; 5,030,557; 5,185,439; 5,283,174; 5,288,611; 5,399,491; 5,437,990; 5,480,784; 5,512,445; 5,514,551; 5,556,771; 5,567,587; 5,585,481; 5,601,984; 5,612,200; 5,614,387; 5,639,604; 5,641,631; 5,656,744; 5,688,645; 5,693,468; 5,696,251; 5,714,324; 5,723,597; 5,834,254; 5,840,488; 5,888,779; 5,948,899; 6,004,745; 6,031,091; 6,090,591; 6,110,678; 6,150,517; 6,280,952; 6,410,276; 6,414,152; RE37,891; 6,512,105; 6,534,273; Australian Patent No. 605743; 613989; 616646; 618965; 619223; 626319; 630076; 633474; 650622; 651371; 699590; 708583; 710884; 726821; 738708; Canadian Patent No. 1,215,904; 1,278,987; 1,314,009; 1,319,336; 1,333,396; 1,339,303; 1,339,871; 1,339,872; 1,340,843; and other international counterparts.

Cat. #1091 APTIMA[®] GC Assay for detection of *Neisseria gonorrhoeae* (100 test kit) U.S. Patent No. 4,851,330; 4,946,958; 4,950,613; 5,030,557; 5,185,439; 5,283,174; 5,288,611; 5,399,491; 5,437,990; 5,480,784; 5,541,308; 5,556,771; 5,567,587; 5,585,481; 5,601,984; 5,612,200; 5,614,387; 5,639,604; 5,641,631; 5,656,744; 5,688,645; 5,696,251; 5,714,324; 5,723,597; 5,834,254; 5,840,488; 5,888,779; 5,948,899; 6,004,745; 6,031,091; 6,090,591; 6,110,678; 6,150,517; 6,280,952; 6,410,276; 6,414,152; RE37,891; 6,512,105; 6,534,273; Australian Patent No. 605743; 613989; 616646; 618965; 619223; 626319; 630076; 633474; 650622; 651371; 699590; 726821; 737017; 738708; Canadian Patent No. 1,215,904;

1,278,987; 1,314,009; 1,319,336; 1,333,396; 1,339,303; 1,339,871; 1,339,872; 1,340,843;
and other international counterparts.

The following products were developed and qualified to be used with the tests listed above and may include proprietary technology. Gen-Probe is the sole source of these kits and reagents.

Cat. #1041 APTIMA® Unisex Swab Specimen Collection Kit for Endocervical and Urethral Swab Specimens

Cat. #1040 APTIMA® Urine Specimen Collection Kit for Male and Female Urine Specimens

Cat. #1162 APTIMA® Vaginal Swab Specimen Collection Kit

Cat. #1154 APTIMA® Specimen Transfer Kit

Cat. #1048 APTIMA® Auto Detection Reagent Kit

Cat. #5575 APTIMA® Urine Collection Tubes, Bulk

The Gen-Probe assays have been validated using the following Gen-Probe instruments: LEADER® 50 and LEADER® 450 Luminometers, and the DTS® 400, 800, and 1600 Systems. The firmware in these instruments is necessary for the running of these assays and is unique to Gen-Probe. We are the sole source of this firmware.

Gen-Probe does not sell through dealers or distributors in the U.S. Sales are made direct to the end user only.

Please do not hesitate to contact me personally if you should need further assistance.

Sincerely,

Brian B. Hansen
Vice President, North American Sales