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STATE PROCUREMENT OFFICE
NOTICE & REQUEST FOR SOLE SOURCE

STATE PROCUREMENT OFFICE
STATE OF HAWAII

- 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: \$500,000

6. Term of Contract: (mm/dd/yyyy) From: CPO Approval To: 12 MONTHS
7. Prior Sole Source Ref No. 09-057-D

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 tests kits are designed to provide laboratory evidence of infection by microbial agents. The analytical method used in these tests 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 the 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 species, produces highly accurate results. The use of the procedure is rapid and accurate.
(continued on attached sheet)

16.

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. Sole source contracts in excess of \$100,000 require cost or pricing data pursuant to HAR Chapter 3-122, subchapter 15. Department is reminded that procurements \$2,500 or more are required to be posted on the Procurement Reporting System.

17.

APPROVED DISAPPROVED NO ACTION REQUIRED

Andrew J. Taylor 5/28/2010
Chief Procurement Officer Date

REQUEST FOR SOLE SOURCE

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

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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 reduced 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 to test non-invasive specimens. This will allow for testing of patients from areas where the collection of specimens requiring invasive procedures are not available.

This product is also the only known USFDA approved product that allows 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.



GEN-PROBE

Thursday, March 04, 2010

State of Hawaii Department of Health
 ATTN: Gail Kunimoto
 2725 Waimano Home Road, 2nd Floor
 Pearl City, HI 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. #301032 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. #301088 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. #301091 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.



GEN-PROBE

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. #301041 APTIMA[®] Unisex Swab Specimen Collection Kit for Endocervical and Urethral Swab Specimens

Cat. #301040 APTIMA[®] Urine Specimen Collection Kit for Male and Female Urine Specimens

Cat. #301162 APTIMA[®] Vaginal Swab Specimen Collection Kit

Cat. #301154C APTIMA[®] Specimen Transfer Kit

Cat. #301048 APTIMA[®] Auto Detection Reagent Kit

Cat. #105575 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

Rev 09.xx.2009

Gen-Probe • 10210 Genetic Center Drive • San Diego, California 92121-4362
(858) 410-8000 • Fax: (858) 288-3141

TOTAL P.002