



STATE PROCUREMENT OFFICE
NOTICE OF AMENDMENT TO SOLE SOURCE CONTRACT

12 JUL 16 A9:52

STATE PROCUREMENT OFFICE
STATE OF HAWAII

TO: Chief Procurement Officer
FROM: HEALTH/STATE LABORATORIES DIVISION
Name of Requesting Department

Pursuant to HRS §103D-306 and HAR chapter 3-122, Subchapter 9, the Department requests an amendment to sole source approval as follows:

1. SPO-001, Sole Source Reference (SS) Number: SS NO. 12-069D
2. Vendor/Contractor/Service Provider Name: Gen-Probe, Inc.
3. Describe the goods, services, or construction.
Laboratory Test Kits & Accessories based on nucleic acid amplification procedures, target capture and dual kinetic assay.

4. Request to amend is submitted in order to:
[checked] Revise the scope of services for the contract as follows:
Additional Laboratory Test Kits & Accessories.
[ ] Increase contract price by 10% or more:
Original Contract Price: Amended Contract F

5. Explain in detail why this/these amendment(s) is/are necessary.
The manufacturer has informed us that they will be upgrading our current system to include the PANTHER System and has added additional reagents and accessories to the original sole source request. See attached.

6. Identify the primary individual(s) who is knowledgeable about this request, who will conduct and manage this process, and has 1) appropriate written delegated procurement authority; 2) completed mandatory training and 3) who SPO may contact for follow up inquiry, if any.
(Type over "example" and delete cells not used.)

Table with 4 columns: Department Personnel Name, Division/Agency, Phone Number, E-mail Address. Row 1: Gail Kunimoto, Health, 453-6700, gail.kunimoto@doh.hawaii.gov

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

All requirement/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.
[Signature] JUL 13 2012
POV Department Head Signature Date

**For Chief Procurement Officer Use Only**

Date Notice Posted: 7/16/2012

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:

Sole source contracts in excess of \$100,000 require cost or pricing data pursuant to HAR chapter 3-122, subchapter 15 and is required to be documented in the procurement/contract file. 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 be compliant on the Hawaii Compliance Express) and award is required to be posted on the Awards Reporting System.

If there are any questions, please contact Kevin Takaesu at 586-0568, or [kevin.s.takaesu@hawaii.gov](mailto:kevin.s.takaesu@hawaii.gov).

Approved       Disapproved     

Kevin Takaesu      7/24/2012  
Chief Procurement Officer Signature      Date



# GEN-PROBE

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Friday, June 29, 2012

State of Hawaii Dept. of Health  
Attn: Gail Kunimoto  
2725 Waimano Home Road  
Pearl City, HI 96782

Dear Gail:

This letter is to verify that Gen-Probe Incorporated is the sole source of the fully automated, nucleic acid-based system and associated kits and reagents listed below for use in determining the presence of *Chlamydia trachomatis* and/or *Neisseria gonorrhoeae* in a test sample.

## Instrument System

Cat. #303095 PANTHER® System  
is covered by U.S. Patent No. 6,605,213, 7,135,145, 7,033,820, and 7,638,337.

## Assay Kit for Use on the Instrument System

Cat. #303094 APTIMA COMBO 2® Assay for detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* (250 test kit), and Cat. #302923 APTIMA COMBO 2® Assay for detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* (100 test kit) are covered by one or more of the following patents: U.S. Patent No. 5,514,551, 5,541,308, 5,556,771, 5,656,207, 5,658,737, 5,693,468, 5,696,251, 5,723,597, 5,756,709, 5,834,254, 5,840,873, 6,090,591, 7,087,742, 7,138,516, and 7,172,863.

The APTIMA Assays have been validated for use with the PANTHER System. The firmware in the PANTHER System is necessary for running the APTIMA Assays and is unique to Gen-Probe. Gen-Probe is the sole source of this firmware.

## Kits and Reagents Associated with the Assay Kits

The following kits and reagents were developed and qualified to be used with the APTIMA Assays 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. #301162 APTIMA® Vaginal Swab Specimen Collection Kit  
Cat. #301154C APTIMA® Specimen Transfer Kit  
Cat. #301048 APTIMA® Auto Detection Reagent Kit  
Cat. #301110 APTIMA® Controls Kit  
Cat. #303001 APTIMA® Assay Fluids Kit  
Cat. #303000 APTIMA® Auto Detect Kit



## GEN-PROBE

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Cat. #303096 PANTHER® System Run Kit  
Cat. #303085 Advanced Cleaning Solution  
Cat. #303099 PANTHER® System Start-Up kit

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

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

Sincerely,

for Brian B. Hansen  
Senior Vice President, Global Sales and Service



# GEN-PROBE

Thursday, March 04, 2010

State of Hawaii Department of Health  
 ATTN: Gail Kunimoto  
 2725 Waimano Home Road, 2<sup>nd</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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

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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<sup>®</sup> Unisex Swab Specimen Collection Kit for Endocervical and Urethral Swab Specimens
- Cat. #301040 APTIMA<sup>®</sup> Urine Specimen Collection Kit for Male and Female Urine Specimens
- Cat. #301162 APTIMA<sup>®</sup> Vaginal Swab Specimen Collection Kit
- Cat. #301154C APTIMA<sup>®</sup> Specimen Transfer Kit
- Cat. #301048 APTIMA<sup>®</sup> Auto Detection Reagent Kit
- Cat. #105575 APTIMA<sup>®</sup> Urine Collection Tubes, Bulk

The Gen-Probe assays have been validated using the following Gen-Probe instruments: LEADER<sup>®</sup> 50 and LEADER<sup>®</sup> 450 Luminometers, and the DTS<sup>®</sup> 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

SS12.0001/001