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STATE OF HAWAII REQUEST FOR SOLE SOURCE

TO: Chief Procurement Officer

FROM: Department of Health/State Laboratories Division/Medical Microbiology Branch

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

STATE PROCUREMENT OFFICE
STATE OF HAWAII

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Description of goods, services, or construction:

NUCLEIC ACID BASED TEST KITS
(Laboratory Test Kits based on nucleic acid amplification procedures, target capture and dual kinetic assay)

Name of Vendor:	GEN-PROBE, INC	Cost: Approximately Three Hundred Thousand Dollars (\$300,000)
Address:	10210 Genetic Center Drive San Diego, California 92121-4362	

Term of contract: From: March 1, 2005 To: February 28, 2006.	Prior Sole Source Reference No.(s) 04-38-M, 03-45-J, 02-45-R
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The goods, services, 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 smaller 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 use specially 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 phenomena 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 this product allows for the use of a dual kinetic assay. This allows for the detection of both *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in 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.

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How the unique features, characteristics, or capabilities are essential for the agency to accomplish its work:

These kits are principally unique in their 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. This product is also FDA approved for a longer specimen transport and storage period of time than other products. All other known products require testing within 7 days of collection and this product allows 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 the 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. This will allow the Department's control program to evaluate the incidence of disease in geographic areas that have not been tested.

The following other possible sources for the goods, services 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. Also, the specimen transport times for all other FDA approved products are limited to 7 days from date of collection.

Direct questions to: GAIL Y. KUNIMOTO, Chief, Medical Microbiology Branch Phone: (808) 453-6700

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

JAN 31 2005

Department/Agency Head

Date

Title (If other than Department/Agency Head)

Chief Procurement Officer's Comments:

Please ensure adherence to applicable administrative and statutory requirements

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

Approved Denied

Alan S. Fyfe 2/14/05
Chief Procurement Officer Date