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STATE OF HAWAII
REQUEST FOR SOLE SOURCE

'04 SEP 28 A10 :21

STATE PROCUREMENT OFFICE
STATE OF HAWAII

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:

Description of goods, services, or construction:

GENETIC PROBE TEST KITS
(Microbial Test kits based upon the unique genetic material of each species of micro-organism)

Name of Vendor:	**GEN-PROBE, INC**	Cost: **Approximately One Hundred Thousand Dollars ($100,000)**
Address:	10210 Genetic Center Drive San Diego, California 92121-4362	

Term of contract: From: **October 15, 2004** To: **October 14, 2005**	Prior Sole Source Reference No.(s) 04-10-J, 03-37-J, 02-26J, 01-23J, 00-17R, 99-27-J, 98-54R

The goods, services, or construction has the following unique features, characteristics, or capabilities:

The test kits are used to identify microbial agents causing disease through a matching of their genetic material.

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, known as probes, the results are objective and highly accurate. The technology was originally developed and marketed to identify micro-organisms. Currently the Medical Microbiology Branch uses test kits to identify difficult to grow organisms, such as *Chlamydia trachomatis, Mycobacteria spp.* and *Neisseria gonorrhoeae.* The use of these kits allow for the rapid diagnoses of patients, however without the ability to recover the organism. In the instance of *Chlamydia trachomatis*, the expense and time involved in trying to recover the organism would not be in the best interest of the patient. In these cases, the use of genetic probe based test kits is the most cost effective method of providing a laboratory diagnosis of disease.

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REQUEST FOR SOLE SOURCE (Cont.)

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

The use of these kits are the essential step in the identification of micro-organisms, as they are a rapid, accurate means of providing laboratory identification of pathogenic agents. The rapid, accurate identification of pathogens is critical to the treatment and medical management of patients and more importantly, confirms the presence of specific pathogens in a community. The purpose of the public health laboratories is to assist the Department of Health's disease monitoring and intervention efforts in the area of communicable diseases. Due to the nature of most communicable diseases, early identification of the causative agent is key to the rapid mobilization of intervention efforts, to prevent wide spread involvement of the population. The lack of the genetic probes will necessitate the use of less accurate, more time consuming methodologies. These methodologies rely on the growth and metabolic characteristics of the organisms, which may be subject to variances in nutritional and environmental factors. At the present time, GEN-PROBE is the only known manufacturer of genetic probe kits for this type of work.

The following other possible sources for the goods, services or construction were investigated, but do not meet our needs because:

There are no other sources for this material. The only known alternative is for the Department to assemble individual components, validate all the components, develop a procedure which does not infringe on any patents and obtain necessary approvals for the use of the procedure. All of this makes it cost prohibitive.

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 constuction are available through only one source.

Linda Rose MD, MPH — SEP 27 2004

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 X No ____. If no, a contract must be executed and funds certified.

X Approved ____ Denied

Chief Procurement Officer — 10/6/04 Date

SPO Form-1 (Rev. 6/98)

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