STATE PROCUREMENT OFFICE
NOTICE & REQUEST FOR SOLE SOURCE

1. TO: Chief Procurement Officer

2. FROM: Health/State Laboratories/Medical Microbiology Branch
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:
GENETIC PROBE TEST KITS (Microbial Test kits based upon the unique genetic material of each species of microorganism)

4. Vendor Name: GEN-PROBE, INC. Address: 10210 Genetic Center Drive San Diego, California 92121-4362	5. Price: $100,000
6. Term of Contract: (mm/dd/yyyy) From: CPO Approval To: 12 Months	7. Prior Sole Source Ref No. 08-030J

SPO-01 (Rev. 7/28/2008)

10. S.S. No. 09-019-C

8. Feature: The good, service, or construction has the following unique features, characteristics, or capabilities: The State Laboratories' equipment and instrumentation are proprietary to the manufacturer. No other products are USFDA approved to be used with this equipment.
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 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 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 phenomenon 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 develped and marketed to identify microorganisms. 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 diagnosis of patients, however, without the ability to recover the organism.

9. Essential features. 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 microorganisms, as they are a rapid, accurate means of providing laboratory identificaiton of pathogenic agents. The rapid, accurate identification of pathogens is critical to the treatment and management of patients and more importantly, confirms the presence of specific pathogens in the 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 (see attached sheet).

11. Alternate source. The following other possible sources for the good, service, or construction were investigated but do not meet our needs because: There are no other sources for this material.

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

   The use of genetic probe based test kits is one of the most cost effective methods of providing a laboratory diagnosis of disease.

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

   of genetic probe kits for this type of work.

12. **Direct any inquiries to:** Department: Health Contact Name/Title: Gail Y. Kunimoto,Chief, Medical Micro	13 Phone Number: 453-6700 Fax Number: 453-6716
Expenditure may be processed with a purchase order/p-Card: ☒ 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 — Date: OCT - 3 2008

Reserved for SPO Use Only

15 Date Notice Posted: 10/10/08

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

16. Chief Procurement Officer's comments:

This approval is based on the DOH State Laboratory's representation that these testing kits are USFDA approved, are essential for their work and can only use kits purchased from the DOH's equipment's manufacturer due to proprietary features.

17.

☒ **APPROVED** ☐ **DISAPPROVED** ☐ **NO ACTION REQUIRED** — Chief Procurement Officer — Date: 10/17/08