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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:
Materials, reagents and supplies for the Isolation, Identification and Drug Susceptibility Testing of Acid Fast Bacilli (AFB)

4. Vendor Name: Becton Dickinson Diagnostics
Address: 7 Loveton Road
Sparks, Maryland 21152-0999

5. Price:
\$75,000

6. Term of Contract:
(mm/dd/yyyy) From: CPO APPROVAL To: 12 MONTHS

7. Prior Sole Source Ref No.
08-032J

8. Feature: The good, service, or construction has the following unique features, characteristics, or capabilities: The BACTEC system is proprietary to Becton Dickinson Diagnostics and is not compatible for use with any other manufacturer's test kits and reagents.

The BACTEC system is the only USFDA cleared diagnostic system for the detection, isolation, presumptive identification and drug susceptibility of Mycobacterium spp. organisms. The system uses a measurement of a metabolite to detect growth and the presumptive identification of Mycobacteria, especially *M. tuberculosis* complex organisms. This is accomplished by measuring the metabolic by product produced by the organism. The organism utilizes nutrients provided in a vial and produces waste products in a distinct concentration over a specified time. The BACTEC instrument assays the atmosphere in the vial and measures the amount of by product (waste) produced by the organism in the vial. The rate of increase of the by products, is indicative of the presence of Mycobacteria. The system also allows for the recovery of suspect organism, which is necessary for the determination of drug susceptibility. The suspect organism can be tested in a medium containing a known concentration of antibiotics. Any antibiotic introduced into the medium should inhibit the growth of a susceptible organism. This inhibition can be measured against the growth in a vial without antibiotic. The use of the BACTEC system is recommended by the Centers for Disease Control and Prevention (CDC). Due to the use of liquid media, the growth rates of the suspect organisms is usually faster than those on the conventional solid media.

Currently, the BACTEC system is the only approved system for the rapid determination of drug susceptibility testing of Mycobacteria. Although several other manufacturers have (See Attached Sheet)

9. Essential features. How the unique features, characteristics, or capabilities are essential for the agency to accomplish its work: The 1994 CDC review of the Department's laboratory was critical in regards to the limited use of rapid diagnostic techniques. The BACTEC system is the only available procedure for the rapid recovery of acid fast bacilli (AFB) which also allows for a presumptive identification of the organism and provides a system to perform drug susceptibilities. AFBs are a group of organisms which include all the members of the Mycobacterium Genus, including those of *M. tuberculosis* complex. The definitive identification of the isolates is normally performed through the use of genetic probes or high performance liquid chromatography techniques.

The use of the BACTEC system and the genetic probes, greatly reduces the amount of time from the receipt of the specimen in the laboratory to the reporting of drug susceptibility results. Conventional techniques for isolating Mycobacteria requires 2-3 months for completion of testing. The use of BACTEC reduces this time by more than 50%. The current medical management practice is the administration of multiple drugs until (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: No other manufacturer exists, whose system is USFDA approved for the isolation, identification and drug susceptibility testing of AFB. The Organon Teknika system, which is capable of rapid isolation and presumptive identification was evaluated and does not meet the program requirements. The system is not approved for drug susceptibilities and showed significantly lower recovery rates for Mycobacterium tuberculosis isolates.

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

developed systems for the rapid diagnosis of Mycobacterial agents, none of these systems are approved by the USFDA for drug susceptibility use.

The BACTEC system represents the least problematic system compatible for the rapid recovery of the agent and the rapid drug susceptibility procedures. The BACTEC system is also compatible with existing identification systems, such as genetic based probes.

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

There is evidence of the drug resistance characteristics of the infecting agent. This practice is estimated to cost approximately \$2,800 per person. A great program savings can be realized by reducing the number of drugs used and length of time they are administered. This is the only system providing rapid growth and isolation of suspect organisms and also yields viable organisms for the conduct of drug susceptibility testing.

REQUEST FOR SOLE SOURCE (Cont.)

Submit in Duplicate

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
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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.

[Handwritten Signature]
Department Head Signature

9/30/08
Date

Reserved for SPO Use Only

15 Date Notice Posted: 10/7/08

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 are the only USFDA approved systems, is essential for their work and available from only this vendor.

17.

APPROVED DISAPPROVED NO ACTION REQUIRED

[Handwritten Signature] 10/14/08
Chief Procurement Officer Date