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STATE OF HAWAII
REQUEST FOR SOLE SOURCE

'05 SEP 15 A8:18

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:

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

Name of Vendor: **Becton Dickinson Diagnostics (Johnston Laboratories)** Address: 7 Loveton Road Sparks, Maryland 21152-0999	Cost: **Approximately Seventy Five Thousand Dollars ($ 75,000).**

Term of contract: From: ~~October 15, 2005~~ Upon CPO Approval To: **October 14, 2006**	Prior Bid Exemption Reference No.(s): 05-22-J, 04-9-J, 03-38-J, 02-25J, 01-20J, 00-16R, 99-26-R, 98-53R, 97-55R, 95-218-R, 94-589-J.

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

The BACTEC system is the only USFDA cleared rapid diagnostic system for the detection, isolation, presumptive identification and drug susceptibility of *Mycobacteria 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 the 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 the antibiotic. The use of the BACTEC system is recommended by the Centers for Disease Control and Prevention (CDC). Due to the use of a liquid media, the growth rates of the suspect organisms is usually faster than those on the conventional solid media.

The BACTEC system, currently is the only approved system for the rapid determination of drug susceptibility testing of *Mycobacteria*. Although several other manufacturers have developed systems for the rapid diagnosis of Mycobacterial agents, none of these systems are approved by the USFDA for drug susceptibility use. The ability to test for drug resistance is necessary to properly treat patients infected by *Mycobacteria*. 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 also is compatible with existing identification systems, such as genetic based probes.

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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 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 the all members of the Mycobacterium Genus, including those of the *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 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.

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

No other manufacturer exists, whose system is USFDA approved for 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 *Mycobaterium tuberculosis* isolates.

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.

Department/Agency Head — Date: SEP 14 2005

Title (If other than Department/Agency Head)

Chief Procurement Officer's Comments:

This approval is based on DOH's representation that this system has been recommended by the CDC and that they are not aware of any other manufacturer that has a similar system approved by the USFDA.

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 — Date: 9/22/05

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SPO Form-1 (6/98)