



APR -7 P2:11

STATE PROCUREMENT OFFICE
NOTICE & REQUEST FOR SOLE SOURCE

PROCUREMENT OFFICE
STATE OF HAWAII

- 1. TO: Chief Procurement Officer
2. FROM: Health/State Laboratories/Medical Microbiology
Department/Division/Agency

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

3. Description of goods, services, or construction:
GEN-PROBE AMPLIFIED MYCOBACTERIUM TUBERCULOSIS DIRECT (MTD) TEST

Table with 2 columns: Vendor Name, Address, Price, Term of Contract, Prior Sole Source Ref No.

8. Feature: The good, service, or construction has the following unique features, characteristics, or capabilities:
Our equipment is proprietary to Gen-Probe. No other test kits are compatible with our instrumentation. The test kits are designed to provide laboratory evidence of infection by microbial agents. The analytical method used in these 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 small amounts of the agent in the specimen. The concept of target capture decreases the possibility of amplification of an incorrect genetic material, which could lead to false positive findings.
The GEN-PROBE AMPLIFIED Mycobacterium Tuberculosis Direct (MTD) Test is a target-amplified nucleic acid probe test and is the only USFDA approved product for the in vitro diagnostic detection of Mycobacterium tuberculosis complex rRNA in acid-fast bacilli (AFB) smear positive and negative concentrated sediments prepared from sputum (induced or expectorated), bronchial specimens (e.g. bronchoalveolar lavages or bronchial aspirates) or tracheal aspirates.

**REQUEST FOR SOLE SOURCE (Cont.)**

9. Essential features. How the unique features, characteristics, or capabilities are essential for the agency to accomplish its work: The MTD test utilizes Transcription-Mediated Amplification (TMA) and the Hybridization Protection Assay (HPA) to qualitatively detect *M. tuberculosis* complex ribosomal ribonucleic acid (rRNA). The MTD test will detect rRNA from both cultivable and non-cultivable organisms. Organisms of the *M. tuberculosis* complex could include *M. tuberculosis*, *M. bovis*, *M. bovis* BCG, *M. africanum*, *M. microti*, and *M. canetti*. The MTD test can detect all organisms with the *M. tuberculosis* complex. However, *M. microti* infects only animals. *M. bovis* is uncommonly transmitted from infected animals to humans, and *M. africanum* causes pulmonary disease in humans in tropical Africa. *M. canetti* was recently described as a member of the *M. tuberculosis* complex, although rarely described as an etiologic agent of disease. *M. tuberculosis* is by far the most common member of the complex that is responsible for human disease worldwide. The CDC has reported a rise in the incidence of tuberculosis associated with AIDS, foreign-born cases, and increased transmission in higher risk populations. (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 none.

12. Direct any inquiries to:  
 Department: Health  
 Contact Name/Title: Gail Y. Kunimoto, Chief, Medical Microbiology

13 Phone Number:  
453-6700  
 Fax Number:  
453-6716

Expenditure may be processed with a purchase order/pCard:  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

4/7/11  
 Date

**Reserved for CPO Use Only**

15 Date Notice Posted: ~~4/11/11~~ 4/13/11

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

REQUEST FOR SOLE SOURCE (Cont.)

16. Chief Procurement Officer's comments:

This approval is for the solicitation process only, HRS section 103D-310(c) and HAR section 3-122-112, shall apply and award is required to be posted on the Awards Reporting System.

17.  APPROVED     DISAPPROVED     NO ACTION REQUIRED

David. Fujita  
Chief Procurement Officer

6/27/2011  
Date

REQUEST FOR SOLE SOURCE

GEN-PROBE AMPLIFIED Mycobacterium Tuberculosis Direct (MTD) Test

March 29, 2011

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

There has been a rise in the number of *M. tuberculosis* strains that are resistant to one or more than one antituberculosis drugs. The public health implications of these facts are considerable.

Conventional culture methodologies can detect tuberculosis growth as early as 1 week, but may take up to 8 weeks. Comparatively, the MTD test provides detection of *M. tuberculosis* complex rRNA within 2.5 to 3.5 hours after beginning the procedure. Although the MTD test cannot ascertain drug susceptibility, it can result in rapid and reliable detection of *M. tuberculosis*. This could lead to more appropriate use of isolation facilities, more appropriate initiation of therapy, and earlier detection and containment of infected contacts.



# GEN-PROBE

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Tuesday, March 22, 2011

State of Hawaii Department of Health  
ATTN: Gail Kunimoto  
2725 Waimano Home Road, 2<sup>nd</sup> Floor  
Pearl City, HI 96782

Dear Gail:

Gen-Probe Incorporated would like to verify that we are the sole source for the following products, which utilize proprietary technology, including technology contained in but not limited to one or more of the following patents:

- Cat. #102810 ACCUPROBE<sup>®</sup> *Campylobacter* Culture Identification Test (20 test kit) U.S. Patent No. 4,851,330; 4,946,958; 5,030,557; 5,185,439; 5,283,174; 5,567,587; 5,585,481; 5,601,984; 5,639,604; 5,656,744; 5,674,684; 5,688,645; 5,696,251; 5,714,324; 5,723,597; 5,840,488; 5,948,899; 6,004,745; 6,031,091; Australian Patent No. 605743; 613989; 619223; 630076; 633474; 651371; Canadian Patent No. 1,215,904; 1,278,987; 1,313,009; 1,319,336; 1,339,303; 1,339,871; 1,339,872.
- Cat #102815 ACCUPROBE<sup>®</sup> *Enterococcus* Culture Identification Test (20 test kit) U.S. Patent No. 4,851,330; 4,946,958; 5,030,557; 5,185,439; 5,283,174; 5,567,587; 5,585,481; 5,601,984; 5,639,604; 5,656,744; 5,688,645; 5,696,251; 5,714,324; 5,723,597; 5,840,488; 5,948,899; 6,004,745; 6,031,091; 6,150,517; Australian Patent No. 605743; 613989; 616646; 619223; 630076; 633474; 651371; Canadian Patent No. 1,215,904; 1,278,987; 1,314,009; 1,319,336; 1,339,303; 1,339,871; 1,339,872.
- Cat #102825 ACCUPROBE<sup>®</sup> *Haemophilus influenzae* Culture Identification Test (20 test kit) U.S. Patent No. 4,851,330; 4,946,958; 5,030,557; 5,185,439; 5,283,174; 5,288,611; 5,472,843; 5,567,587; 5,585,481; 5,601,984; 5,639,604; 5,656,744; 5,688,645; 5,696,251; 5,714,324; 5,723,597; 5,830,654; 5,840,488; 5,948,899; 6,004,745; 6,031,091; Australian Patent No. 605743; 613989; 619223; 630076; 633474; 651371; Canadian Patent No. 1,215,904; 1,278,987; 1,314,009; 1,319,336; 1,339,303; 1,339,871; 1,339,872.
- Cat# 102830 ACCUPROBE<sup>®</sup> *Neisseria gonorrhoeae* Culture Identification Test (20 test kit) U.S. Patent No. 4,851,330; 4,946,958; 5,030,557; 5,185,439; 5,283,174; 5,288,611; 5,541,308; 5,567,587; 5,585,481; 5,601,984; 5,639,604; 5,656,744; 5,688,645; 5,696,251; 5,714,324; 5,723,597; 5,840,488; 5,948,899; 6,004,745; 6,031,091; 6,150,517; Australian Patent No. 605743; 613989; 616646; 619,223; 625739; 630076; 633474; 651371; Canadian Patent No. 1,215,904; 1,278,987; 1,296,604; 1,314,009; 1,319,336; 1,339,303; 1,339,871; 1,339,872.
- Cat# 102865 ACCUPROBE<sup>®</sup> *Streptococcus pneumoniae* Culture Identification Test (20 test kit) U.S. Patent No. 4,851,330; 4,946,958; 5,030,557; 5,185,439; 5,283,174; 5,288,611; 5,567,587; 5,585,481; 5,601,984; 5,639,604; 5,656,744; 5,688,645; 5,696,251; 5,714,324; 5,723,597; 5,738,987; 5,840,488; 5,948,899; 6,004,745; 6,031,091; Australian Patent No. 605743; 613989; 619223; 630076; 633474; 651371; Canadian Patent No. 1,215,904; 1,278,987; 1,314,009; 1,319,336; 1,339,303; 1,339,871; 1,339,872.
- Cat# 102875 ACCUPROBE<sup>®</sup> *Staphylococcus aureus* Culture Identification Test (20 test kit) U.S. Patent No. 4,851,330; 4,946,958; 5,030,557; 5,185,439; 5,283,174; 5,288,611; 5,292,874; 5,567,587; 5,582,975; 5,585,481; 5,601,984; 5,639,604; 5,656,744; 5,688,645; 5,696,251;



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- 5,714,324; 5,723,597; 5,840,488; 5,948,899; 6,004,745; 6,031,091; 6,150,517; Australian Patent No. 605743; 613989; 619223; 630076; 633474; 651371; Canadian Patent No. 1,215,904; 1,278,987; 1,314,009; 1,319,336; 1,339,303; 1,339,871; 1,339,872.
- Cat# 102890 ACCUPROBE® *Blastomyces dermatitidis* Culture Identification Test (20 test kit) U.S. Patent No. 4,851,330; 4,946,958; 5,030,557; 5,185,439; 5,283,174; 5,374,522; 5,558,990; 5,585,481; 5,601,984; 5,639,604; 5,656,744; 5,688,645; 5,696,251; 5,714,324; 5,723,597; 5,840,488; 5,948,899; 6,004,745; 6,031,091; 6,150,517; 6,414,152; 6,512,105; Australian Patent No. 604684; 605743; 613989; 619223; 625739; 630076; 633474; 651371; Canadian Patent No. 1,215,904; 1,278,987; 1,296,604; 1,314,009; 1,319,336; 1,339,303; 1,339,871; 1,339,872.
- Cat# 102895 ACCUPROBE® *Coccidioides Immitis* Culture Identification Test (20 test kit) U.S. Patent No. 4,851,330; 4,946,958; 5,030,557; 5,185,439; 5,283,174; 5,284,747; 5,288,611; 5,374,522; 5,501,951; 5,585,481; 5,601,984; 5,639,604; 5,656,744; 5,688,645; 5,696,251; 5,714,324; 5,723,597; 5,840,488; 5,948,899; 6,004,745; 6,031,091; Australian Patent No. 604684; 605743; 613989; 616646; 619223; 630076; 633474; 651371; Canadian Patent No. 1,215,904; 1,278,987; 1,296,604; 1,314,009; 1,319,336; 1,339,303; 1,339,871; 1,339,872.
- Cat# 102910 ACCUPROBE® *Histoplasma capsulatum* Culture Identification Test (20 test kit) U.S. Patent No. 4,851,330; 4,946,958; 5,030,557; 5,185,439; 5,283,174; 5,288,611; 5,352,579; 5,374,522; 5,585,481; 5,601,984; 5,639,604; 5,656,744; 5,688,645; 5,696,251; 5,714,324; 5,723,597; 5,840,488; 5,948,899; 6,004,745; 6,031,091; Australian Patent No. 604684; 605743; 613989; 616646; 619223; 630076; 633474; 651371; Canadian Patent No. 1,215,904; 1,278,987; 1,296,604; 1,314,009; 1,319,336; 1,339,303; 1,339,871; 1,339,872.
- Cat# 102925 ACCUPROBE® *Group A Streptococcus* Culture Identification Test (20 test kit) U.S. Patent No. 4,851,330; 4,946,958; 5,030,557; 5,185,439; 5,232,831; 5,283,174; 5,288,611; 5,567,587; 5,585,481; 5,601,984; 5,639,604; 5,656,744; 5,688,645; 5,696,251; 5,714,324; 5,723,597; 5,840,488; 5,948,899; 6,004,745; 6,031,091; Australian Patent No. 605743; 613989; 616646; 619223; 625739; 630076; 633474; 651371; Canadian Patent No. 1,215,904; 1,278,987; 1,314,009; 1,319,336; 1,339,303; 1,339,871; 1,339,872.
- Cat. #102820 ACCUPROBE® *Group B Streptococcus* Culture Identification Test (20 test kit) U.S. Patent No. 4,851,330; 4,946,958; 5,030,557; 5,185,439; 5,283,174; 5,567,587; 5,585,481; 5,601,984; 5,612,183; 5,639,604; 5,656,744; 5,688,645; 5,696,251; 5,714,324; 5,723,597; 5,840,488; 5,948,899; 6,004,745; 6,031,091; 6,150,517; Australian Patent No. 605743; 613989; 619223; 625739; 630076; 633474; 651371; Canadian Patent No. 1,215,904; 1,278,987; 1,314,009; 1,319,336; 1,339,303; 1,339,871; 1,339,872.
- Cat. #102820B ACCUPROBE® *Group B Streptococcus* Culture Identification Test (200 test kit) U.S. Patent No. 4,851,330; 4,946,958; 5,030,557; 5,185,439; 5,283,174; 5,567,587; 5,585,481; 5,601,984; 5,612,183; 5,639,604; 5,656,744; 5,688,645; 5,696,251; 5,714,324; 5,723,597; 5,840,488; 5,948,899; 6,004,745; 6,031,091; 6,150,517; Australian Patent No. 605743; 613989; 619223; 625739; 630076; 633474; 651371; Canadian Patent No. 1,215,904; 1,278,987; 1,314,009; 1,319,336; 1,339,303; 1,339,871; 1,339,872.
- Cat. #102835 ACCUPROBE® *Mycobacterium avium* Culture Identification Test (20 test kit) U.S. Patent No. 4,851,330; 4,946,958; 5,030,557; 5,185,439; 5,283,174; 5,288,611; 5,374,522; 5,567,587; 5,593,841; 5,601,984; 5,639,604; 5,656,744; 5,688,645; 5,696,251; 5,714,324; 5,723,597; 5,840,488; 5,948,899; 6,004,745; 6,031,091; 6,150,517; Australian Patent No. 604684; 605743; 613989; 619223; 630076; 633474; 651371; Canadian Patent No. 1,215,904; 1,278,987; 1,296,604; 1,314,009; 1,319,336; 1,339,303; 1,339,871; 1,339,872.

Rev 09.xx.2009



- Cat. #102840 ACCUPROBE® *Mycobacterium Intracellulare* Culture Identification Test (20 test kit)  
U.S. Patent No. 4,851,330; 4,946,958; 5,030,557; 5,185,439; 5,283,174; 5,288,611;  
5,374,522; 5,567,587; 5,585,481; 5,595,874; 5,601,984; 5,639,604; 5,656,744; 5,688,645;  
5,696,251; 5,714,324; 5,723,597; 5,840,488; 5,948,899; 6,004,745; 6,031,091; 6,150,517;  
Australian Patent No. 604684; 605743; 613989; 616646; 619223; 625739; 630076; 633474;  
651371; Canadian Patent No. 1,215,904; 1,278,987; 1,296,604; 1,314,009; 1,319,336;  
1,339,303; 1,339,871; 1,339,872.
- Cat. #102845 ACCUPROBE® *Mycobacterium avium* Complex Culture Identification Test (20 test kit)  
U.S. Patent No. 4,851,330; 4,946,958; 5,030,557; 5,185,439; 5,283,174; 5,374,522;  
5,567,587; 5,585,481; 5,601,984; 5,639,604; 5,656,744; 5,688,645; 5,696,251; 5,714,324;  
5,723,597; 5,948,899; 6,004,745; 6,031,091; 6,150,517; Australian Patent No. 604684;  
605743; 613989; 619223; 630076; 633474; 651371; 689801; Canadian Patent No. 1,215,904;  
1,278,987; 1,296,604; 1,314,009; 1,319,336; 1,339,303; 1,339,871; 1,339,872.
- Cat. #102850 ACCUPROBE® *Mycobacterium gordonae* Culture Identification Test (20 test kit) U.S.  
Patent No. 4,851,330; 4,946,958; 5,030,557; 5,185,439; 5,216,143; 5,283,174; 5,288,611;  
5,374,522; 5,567,587; 5,585,481; 5,601,984; 5,639,604; 5,656,744; 5,688,645; 5,696,251;  
5,714,324; 5,723,597; 5,840,488; 5,948,899; 6,004,745; 6,031,091; 6,150,517; Australian  
Patent No. 604684; 605743; 613989; 616646; 619223; 625739; 630076; 633474; 651371;  
Canadian Patent No. 1,215,904; 1,278,987; 1,296,604; 1,314,009; 1,319,336; 1,339,303;  
1,339,871; 1,339,872.
- Cat. #102855 ACCUPROBE® *Mycobacterium kansasii* Culture Identification Test (20 test kit) U.S.  
Patent No. 4,851,330; 4,946,958; 5,030,557; 5,185,439; 5,283,174; 5,288,611; 5,374,522;  
5,567,587; 5,585,481; 5,601,984; 5,639,604; 5,656,744; 5,681,698; 5,688,645; 5,696,251;  
5,714,324; 5,723,597; 5,840,488; 5,948,899; 6,004,745; 6,031,091; 6,150,517; Australian  
Patent No. 604684; 605743; 613989; 619223; 625739; 630076; 633474; 651371; Canadian  
Patent No. 1,215,904; 1,278,987; 1,296,604; 1,314,009; 1,319,336; 1,339,303; 1,339,871;  
1,339,872.
- Cat. #102860 ACCUPROBE® *Mycobacterium tuberculosis* Complex Culture Identification Test (20  
test kit) U.S. Patent No. 4,851,330; 4,946,958; 5,030,557; 5,185,439; 5,283,174; 5,374,522;  
5,547,842; 5,567,587; 5,585,481; 5,601,984; 5,639,604; 5,656,744; 5,688,645; 5,696,251;  
5,714,324; 5,723,597; 5,840,488; 5,906,917; 5,948,899; 6,004,745; 6,031,091; 6,150,517;  
Australian Patent No. 604684; 605743; 613989; 619223; 630076; 633474; 651371; Canadian  
Patent No. 1,215,904; 1,278,987; 1,296,604; 1,314,009; 1,319,336; 1,339,303; 1,339,871;  
1,339,872.
- Cat. #102920 ACCUPROBE® *Listeria Monocytogenes* Culture Identification Test (20 test kit) U.S.  
Patent No. 4,851,330; 4,946,958; 5,030,557; 5,185,439; 5,283,174; 5,288,611; 5,567,587;  
5,585,481; 5,601,984; 5,612,183; 5,639,604; 5,656,744; 5,688,645; 5,696,251; 5,714,324;  
5,723,597; 5,738,988; 5,738,989; 5,840,488; Australian Patent No. 605743; 613989; 616646;  
619223; 625739; 630076; 633474; 651371; Canadian Patent No. 1,215,904; 1,278,987;  
1,314,009; 1,319,336; 1,339,303; 1,339,871; 1,339,872.
- Cat. #103890 GASDirect® *Group A Streptococcus Direct* Test (100 test kit) U.S.  
Patent No. 4,851,330; 4,946,958; 5,030,557; 5,185,439; 5,232,831; 5,283,174; 5,567,587;  
5,585,481; 5,601,984; 5,639,604; 5,656,744; 5,688,645; 5,696,251; 5,714,324; 5,723,597;  
5,837,452; 5,840,488; 5,948,899; 6,004,745; 6,031,091; Canadian Patent No. 1,215,904;



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1,278,987; 1,314,009; 1,319,336; 1,339,303; 1,339,871; 1,339,872; 2,176,496; Australian Patent No. 605743; 613989; 619223; 625739; 630076; 633474; 651371; 693836.

Cat. #103890B GASDirect® *Group A Streptococcus Direct Test* (500 test kit)

U.S. Patent No. 4,851,330; 4,946,958; 5,030,557; 5,185,439; 5,232,831; 5,283,174; 5,567,587; 5,585,481; 5,601,984; 5,639,604; 5,656,744; 5,688,645; 5,696,251; 5,714,324; 5,723,597; 5,837,452; 5,840,488; 5,948,899; 6,004,745; 6,031,091; Canadian Patent No. 1,215,904; 1,278,987; 1,314,009;

Cat. #301001 AMPLIFIED MTD® *Mycobacterium tuberculosis Direct Test* (50 test kit)

U.S. Patent No. 4,851,330; 4,946,958; 4,950,613; 5,030,557; 5,185,439; 5,283,174; 5,374,522; 5,399,491; 5,437,990; 5,480,784; 5,547,842; 5,556,771; 5,567,587; 5,585,481; 5,601,984; 5,612,200; 5,614,387; 5,639,604; 5,656,744; 5,688,645; 5,696,251; 5,723,597; 5,766,890; 5,846,701; 5,871,975; 5,888,779; 5,908,744; 5,948,899; 6,004,745; 6,031,745; 6,031,091; 6,090,591; 6,150,517.

The following products were developed and qualified to be used with the tests listed above and may include proprietary technology. Gen-Probe is the sole source of these kits and reagents.

Cat. #102930 Fast Express Reagent

Cat. #201791 GEN-PROBE® Detection Reagent Kit

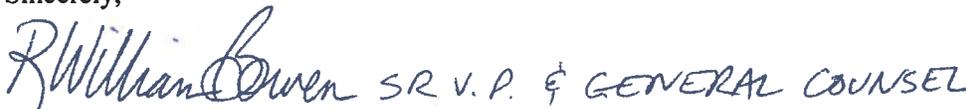
Cat. #102800 ACCUPROBE® Culture Confirmation Kit

The Gen-Probe assays have been validated using the following Gen-Probe instruments: LEADER® 50 and LEADER® 450 Luminometers. The firmware in these instruments is necessary for the running of these assays and is unique to Gen-Probe. We are the sole source of this firmware.

Gen-Probe does not sell through dealers or distributors in the U.S. Sales are made direct to the end user only.

Please do not hesitate to contact me personally if you should need further assistance.

Sincerely,

 R. William Bowen SR.V.P. & GENERAL COUNSEL

for

Brian B. Hansen

Vice President, Americas and Asia Pacific

Rev 09.xx.2009