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**STATE PROCUREMENT OFFICE**  
**NOTICE & REQUEST FOR SOLE SOURCE**

STATE PROCUREMENT OFFICE  
STATE OF HAWAII

TO: Chief Procurement Officer

FROM: Health/State Laboratories/Medical Microbiology Branch  
*Name of Requesting Department*

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

<p>1. Describe the goods, services, or construction to be procured.</p> <p>Quantiferon -TB Gold In-Tube (IT) Test Kits and Accessories for detection of latent Mycobacterium tuberculosis infection in heparinized whole blood.</p>	
<p>2. Vendor/Contractor Name:           Cellestis, Inc.</p>	<p>3. Amount of Request:</p> <p style="text-align: center;">\$ 100,000</p>
<p>4. Term of contract (shall not exceed 12 months), if applicable:</p> <p style="margin-left: 20px;">From:           CPO APPROVAL                    To:   12 MONTHS</p>	<p>5. Prior Sole Source Ref No.:</p> <p style="text-align: center;">10-027-D</p>
<p>6. Features: Describe in detail the unique features, characteristics, or capabilities of the goods, services or construction. It is the only FDA approved blood test for latent TB infections on the market that does not require microscopy (which is too labor intensive) and is automated. The Quantiferon-TB Gold IT software is proprietary to Cellestis, Inc. and cannot be used with any other manufacturer's product. The Quantiferon-TB Gold In-Tube (IT) test is an enzyme-linked immunosorbent assay (ELISA) that detects the release of interferon-gamma (IFN-G) in fresh heparinized whole blood from sensitized persons when incubated with synthetic peptides simulating two proteins present in M. tuberculosis. Because these proteins are absent from Bacille Calmette-Guerin (BCG) vaccine strains and from commonly encountered nontuberculosis mycobacteria (NTM) except for a few species, the Quantiferon-TB Gold IT is expected to be more specific for M. tuberculosis (continued on page 4.)</p>	
<p>7. Essential features: Describe in detail how the unique features, characteristics, or capabilities of the goods, services, or construction are essential for the department to accomplish its work.</p> <p>Testing capabilities for Quantiferon-TB Gold IT will significantly improve our laboratory's ability for the Department's Tuberculosis Control Program to identify and treat patients with latent tuberculosis infection so they do not spread their disease to the public. Quantiferon-TB Gold IT can be used in all circumstances in which TST is used, including contact investigations, evaluation of recent immigrants who have BCG vaccination, and TB screening of health-care workers and others undergoing serial evaluation for M. tuberculosis infection. Quantiferon-TB Gold IT usually can be used in place of TSTs. The TB Control Program can use Quantiferon-TB Gold It for investigating contacts of persons with potentially infectious TB disease. (continued on page 4.)</p>	
<p>8. Describe the efforts and results in determining that this is the only vendor/contractor who can provide the goods, services or construction.</p> <p>Quantiferon-TB Gold IT Test and accessories and its software is proprietary to Cellestis, Inc. and is the only manufacturer and distributor of this product.</p>	

9. Alternate source. Describe the other possible sources for the goods, services, or construction that were investigated but did not meet the department's needs.  
 The T-Spot test manufactured by Oxford Immunotec has been investigated, and has been found to be too labor intensive and too difficult to use in a standardized testing approach statewide.

10. Identify the primary individual(s) who is knowledgeable about this request, who will conduct and manage this process, and has 1) appropriate written delegated procurement authority; and 2) completed mandatory training.  
 (Type over "example" and delete cells not used.)

Name of Department Personnel	Division/Agency	Phone Number	e-mail address
Gail Kunimoto	SLD/MMB	453-6700	gail.kunimoto@doh.hawaii.gov

Department shall ensure adherence to applicable administrative and statutory requirements, including HAR Chapter 3-122, Subchapter 15, Cost or Price Data if required.

*All requirements/approvals and internal controls for this expenditure is the responsibility of the department.*

*I certify that the information provided is to the best of my knowledge, true and correct.*

  
 Department Head Signature

12/27/11  
 Date

**For Chief Procurement Officer Use Only**

11. Date Notice Posted:

12/22/2011

Submit written objection to this notice to issue a sole source contract within seven calendar days or as otherwise allowed from date notice posted to:

Chief Procurement Officer  
State of Hawaii  
P.O. Box 119  
Honolulu, HI 96810-0119

12. Chief Procurement Officer (CPO) Comments:

This approval is based on the department's representation that these manufacturer's kits and accessories are essential for their work and available from only this vendor. 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.

Sole source contracts in excess of \$100,000 require cost or pricing data pursuant to HAR chapter 3-122, subchapter 15. This award is required to be posted on the Awards Reporting System.

Approved       Disapproved       No Action Required

*Alan S. Fajal*  
Chief Procurement Officer Signature

12/29/2011  
Date

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6. Features: Describe in detail the unique features, characteristics, and capabilities of the goods, services or construction.

than tests that use tuberculin protein derivative (PPD) as the antigen.

Tuberculosis is a communicable disease which typically spreads to new hosts via airborne droplet nuclei from patients with respiratory tuberculosis disease. A newly infected individual can become ill from tuberculosis within weeks to months, but most infected individuals remain well. Latent tuberculosis infection (LTBI), a non-communicable asymptomatic condition, persists in some individuals who may develop tuberculosis disease months or years later. The main purpose for diagnosing LTBI is to consider medical treatment for preventing tuberculosis disease. Until recently, the tuberculin skin test (TST) was the only available method for diagnosing LTBI. LTBI must be distinguished from tuberculosis disease which usually involves the lungs and lower respiratory tract, although other organ systems may also be affected. Tuberculosis disease is diagnosed from historical, physical, radiological, histological, and mycobacterial findings.

QFT-G has been approved by the USFDA since 2005 as an aid for diagnosing both latent tuberculosis (LTBI) and TB disease. The tuberculin skin test (TST) was the only test available for detecting LTBI prior to the Quantiferon-TB Gold IT results can be available <24 hours after testing without the need for a second visit, whereas a TST requires a second encounter to read the result 24-72 hours after administration of the test. As a laboratory-based assay, the Quantiferon-TB Gold IT assay is not subject to the biases and errors of TST placement and reading.

TST and Quantiferon-TB Gold IT rely on a different immune response and differs in its relative measures of sensitivity and specificity. The TST assesses in vivo delayed-type sensitivity (Type IV) whereas Quantiferon-TB Gold IT measure in-vitro release of IFN- $\gamma$ . The TST measures response to PPD, a polyvalent antigenic mixture, whereas Quantiferon-TB Gold IT measures a response mixture of synthetic peptides simulating two specific antigenic proteins that are present in PPD. Quantiferon-TB Gold IT is not affected by prior BCG vaccination and is expected to be less influenced by previous infection with non-tuberculosis mycobacteria. TSTs are variably affected by these factors. Quantiferon-TB Gold IT does not trigger an anamnestic response (i.e. boosting) because it does not expose persons to antigen. Injection of PPD for TST can boost subsequent TST responses, primarily in persons who have been infected with NTM or vaccinated with BCG. Compared with the TST, Quantiferon-TB Gold IT might be less affected by boosting from a previous TST.

7. Essential Features: Describe in detail how the unique features, characteristics, and capabilities of the goods, services, or construction are essential for the department to accomplish their work.

Because Quantiferon-TB Gold IT does not require a second visit to complete, test results will probably be available from a greater percentage of contacts than would be available using TST.

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Because of its greater specificity, Quantiferon-TB Gold IT is expected to include a smaller proportion of contacts as infected that the TST would indicate.

Public health resources that were previously devoted to completion of testing can be concentrated on full evaluation and complete treatment of contacts who have positive Quantiferon-TB Gold IT results. In contrast to the TST, initial Quantiferon-TB Gold IT testing of contacts will not boost subsequent test results, which avoids uncertainty without interpreting follow-up results.

Quantiferon-TB Gold IT might represent a cost-effective alternative to TST in testing programs which are part of the TB Infection Control Program in institutions such as health care settings, correctional facilities, or homeless shelters. In these settings, false-positive reactions to TST pose a problem compounded in settings with BCG-vaccinated persons in countries where TB is prevalent. Disadvantages of TST testing include the need for follow-up visits for reading the TST. Advantages of Quantiferon-TB Gold IT includes greater specificity and the requirement for only one visit.

The Hawai'i State Department of Health (DOH) Tuberculosis (TB) Control Branch recently received a \$3.75 million contract to participate in the Centers for Disease Control and Prevention-sponsored Tuberculosis Epidemiological Studies Consortium (TBESC). The DOH was one of ten sites selected nationwide after a highly competitive application process.

This funding is expected to provide additional resources for the TB Control program to provide enhanced services for people with latent TB infection who are at risk for developing and spreading active TB.

It is estimated that up to 10% of all Hawai'i residents have latent TB infection. The treatment of latent TB is difficult, because most people avoid preventive treatment when they don't feel sick. This new grant will allow the DOH to implement innovative methods to diagnose and treat these non-infectious patients throughout the state, before the illness turns into full-blown tuberculosis with serious symptoms and the potential of transmission to other people. This program is expected to enroll 500 to 1,000 participants annually over a seven-year enrollment period. Newly demonstrated treatment methods, such as once-weekly preventive treatment, and use of new TB blood tests for TB infection such as Quantiferon-TB Gold IT will be used in the coming year. Results and recommendations from this new study will help improve efficiency and effectiveness for Hawaii's TB screening procedures and focus state resources on high-risk groups.

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customer.service@cellestis.com  
www.cellestis.com  
Tax ID# 52-2310821

**Re: QuantiFERON®-TB Gold In-Tube test Sole Source**

To Whom It May Concern:

The purpose of this document is to verify that Cellestis Inc. (Valencia, CA) is the sole source supplier in the United States (with the exception of Puerto Rico and the U.S. Virgin Islands) of the QuantiFERON®-TB Gold In-Tube test and other QuantiFERON®-TB test products.

Cellestis Inc. is a U.S. registered company, and the wholly owned subsidiary of Cellestis Limited (Melbourne, Australia).

Cellestis Limited has exclusive rights to the patented QuantiFERON® technology. Cellestis Limited has licenses for exclusive use of tuberculosis specific antigens: ESAT-6, CFP-10 and TB7.7(p4) in the QuantiFERON®-TB Gold In-Tube test, under US Patent no. 5955077 (valid until 2015), 6290969 (valid until 2017), and 6291190 (valid until 2019); respectively.

The Cellestis group has developed the QuantiFERON®-TB Gold In-Tube test kit after extensive pre-clinical and clinical testing within the U.S. and elsewhere.

QuantiFERON®-TB Gold In-Tube was approved by the FDA on October 10, 2007 for diagnosis of tuberculosis infection, replacing the previously approved QuantiFERON®-TB Gold and QuantiFERON®-TB tests.

As a consequence, Cellestis Inc. is the sole source supplier of QuantiFERON®-TB Gold In-Tube, QuantiFERON®-TB Gold and other QuantiFERON® test products within the United States (except Puerto Rico and U.S. Virgin Islands).

Sincerely,

Mark Boyle  
President, Cellestis Inc.

MEASURING THE OTHER SIDE OF IMMUNITY



SS: 12-0418