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STATE PROCUREMENT OFFICE  
NOTICE & REQUEST FOR SOLE SOURCE

STATE PROCUREMENT OFFICE  
STATE OF HAWAII

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:  
Quantiferon ® -TB Gold In-Tube (IT) Test Kits and Accessories for detection of latent Mycobacterium tuberculosis infection in heparinized whole blood.

4. Vendor Name: Cellestis, Inc.  
Address: 28043 Smyth Drive  
Valencia, CA 93155

5. Price:  
\$150,000

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

7. Prior Sole Source Ref No.  
09-022-J

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.

*Christina J. Jenkins, MD*

DEC 21 2009

Department Head Signature

Date

Reserved for SPO Use Only

15 Date Notice Posted: 12/28/09

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:

No action is required by the CPO. This is a duplicate request (see SS-10-027-D).

17.

APPROVED  DISAPPROVED  NO ACTION REQUIRED

*Clara S. Fitch*  
Chief Procurement Officer

1/13/2010  
Date

## SOLE SOURCE REQUEST

Test Kits and Accessories to Detect Latent *Mycobacterium tuberculosis* in Heparinized Whole Blood

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

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 this. 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 measures in vitro release of IFN- $\gamma$ . The TST measure 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 the 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.

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

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 about interpreting follow-up results.

**SOLE SOURCE REQUEST**

**Test Kits and Accessories to Detect Latent *Mycobacterium tuberculosis* in Heparinized Whole Blood**

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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.