



01-017-01-1011

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

1. TO: Chief Procurement Officer
2. FROM: HEALTH/STATE LABORATORIES/MEDICAL MICROBIOLOGY
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.
08-041-J

8. Feature: The good, service, or construction has the following unique features, characteristics, or capabilities: 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 it is incubated with synthetic peptides stimulating 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* 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 usualll 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 mycobacteriological findings. (See Attached Sheet)

9. Essential features. How the unique features, characteristics, or capabilities are essential for the agency to accomplish its work: Development of 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. 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. Because of its greater specificity, Quantiferon ®-TB Gold IT is expected to include a smaller proportion of (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: 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.

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8. 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- γ . 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.

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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.

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.



OCT - 3 2008

Department Head Signature

Date

Reserved for SPO Use Only

15 Date Notice Posted: 10/07/08

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:

Sole source contracts in excess of \$100,000 require cost or pricing data pursuant to subchapter 15, Chapter 3-122, HAR. Questions on this issue may be directed to SPO staff at 586-0577.

17.

APPROVED DISAPPROVED NO ACTION REQUIRED



Chief Procurement Officer

10/15/08
Date



Cellestis Inc.
28043 Smyth Drive
Valencia, CA 91355
800.519.4627 (toll free)
661.775.7480 (phone)
661.775.7479 (fax)
customer.service@cellestis.com
www.cellestis.com

October 22, 2007

Harry Domen
State of HI, Dept. of Health Lab
Medical Microbiology Branch
2725 Waimano Home Rd., 2nd floor
Pearl City, HI 96782

Dear Harry,

We are pleased to announce the FDA approval of our QuantiFERON-TB Gold In-Tube blood test.

These In-Tube kits include:

0590 0301	QuantiFERON®-TB Gold Tubes (Nil, TB Antigen, Mitogen, 100 each)
0594 0201	QuantiFERON®-TB Gold ELISA kit - runs up to 58 samples.

Cellestis Inc. is the developer, manufacturer, and sole provider of these kits in the United States – and worldwide.

More information about our company and our products can be found at www.cellestis.com

Thanks.

Patrice Hall

Patrice Hall
Regional Sales Manager
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