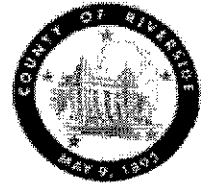


**SUBMITTAL TO THE BOARD OF SUPERVISORS  
COUNTY OF RIVERSIDE, STATE OF CALIFORNIA**

232



**FROM:** Community Health Agency/Department of Public Health

**SUBMITTAL DATE:**  
October 20, 2008

**SUBJECT:** APPROVAL OF THE AGREEMENT BETWEEN CELLESTIS INC. AND THE COMMUNITY HEALTH AGENCY/DEPARTMENT OF PUBLIC HEALTH LABORATORY FOR THE PURCHASE OF QUANTIFERON TB GOLD IN-TUBE TEST KITS AND REAGENTS.

**RECOMMENDED MOTION:** That the Board of Supervisors:

1. Approve the purchase of QuantiFERON-TB Gold In-Tube test kits and reagents without securing competitive bids, in accordance with Ordinance No. 459.4, in the estimated annual amount of \$96,000, to Cellestis Inc pursuant to the Purchasing Agent approving this purchase on behalf of the County; and
2. Authorize the County Purchasing Agent to renew the contract annually for a maximum three year contract provided the per test cost increase does not exceed the CPI.

Departmental Concurrence

(Continued)

*Susan D. Harrington*

BL:jt

Susan Harrington  
Director, Department of Public Health

<b>FINANCIAL DATA</b>	Current F.Y. Total Cost:	\$ 64,000.00	In Current Year Budget:	Yes
	Current F.Y. Net County Cost:	\$ 64,000.00	Budget Adjustment:	No
	Annual Net County Cost:	\$ 96,000.00	For Fiscal Year:	08/09

<b>SOURCE OF FUNDS:</b> Net County Cost. Cost of testing will be off-set by laboratory charges.	Positions To Be Deleted Per A-30	—
	Requires 4/5 Vote	<input type="checkbox"/>

**C.E.O. RECOMMENDATION:**

APPROVE

BY: *Debra Cournoyer*  
Debra Cournoyer

**County Executive Office Signature**

Dept'l Recomm.:  Consent  Policy  
 Per Exec. Ofc.:  Consent  Policy

Prev. Agn. Ref.: \_\_\_\_\_ District: \_\_\_\_\_ Agenda Number: \_\_\_\_\_

**3.16**

**BACKGROUND:** Tuberculosis (TB) is a communicable disease caused by *Mycobacteria tuberculosis*. This agent spreads to new hosts via airborne droplet nuclei. A newly infected person can become ill or may remain well for some time. Latent tuberculosis infection (LTBI) is non-communicable and asymptomatic, but diagnosis of LTBI is important to consider medical treatment for preventing tuberculosis disease. Until recently, the tuberculin skin test (TST) was the only available method for diagnosing LTBI. Some LTBI patients with decreased immune function do not respond to the TST (giving a false negative). Patients who have been vaccinated with BCG or have had other forms of *Mycobacteria* usually react from the TST (giving a false positive).

The QuantiFERON-TB Gold In-Tube (QFT) test is a second generation QuantiFERON test that uses specially designed specimen collection tubes that are coated with *M.tuberculosis* specific antigens. This provides an indirect test that measures an interferon release that occurs in response to the patient's blood being stimulated by the *M.tuberculosis* antigens. This test is not affected by the BCG vaccine or other mycobacterial infections. This makes the QuantiFERON-TB Gold In-Tube test highly specific for detecting *M.tuberculosis* infection.

QuantiFERON-TB Gold In-Tube test is intended to aid in tuberculosis patient management along with clinical history, risk assessment, chest x-ray and other medical evaluations.

Cellestis is the sole provider of the QuantiFERON-TB Gold In-Tube test.

**Justification:** Cellestis has proprietary rights to these products and technology. Cellestis Inc., located in Valencia, California is a U.S. registered company, and the wholly owned subsidiary of Cellestis Ltd., Melbourne, Australia owns all rights to the patented QuantiFERON technology, which the patent is valid in the U.S. until 2017.

QuantiFERON-TB Gold In-Tube is cost effective for TB infection control programs. The QFT requires only one patient visit in contrast to the TST which can require up to 4 visits due to 2-step boosting. Personnel and investigative costs are reduced due to the elimination of false positive results. False positives can involve follow-up testing that includes chest x-rays and unnecessary TB therapy.

**Price Reasonableness:** Cellestis Inc. is offering a \$2.00 per test discount off their normal State and local government pricing to the County of Riverside, whereby the County shall pay \$20.00 per test instead of the \$22.00 per test rate. The pricing offered by Cellestis Inc. is fair and reasonable.

Date: October 17, 2008  
From: Janna Troy Department/Agency: \_CHA Laboratory  
To: Board of Supervisors  
Via: Purchasing Agent  
Subject: Sole Source Procurement; Request for QuantiFERON TB Test

The below information is provided in support of my Department requesting approval for a sole source. Outside of a duly declared emergency, the time to develop a statement of work or specifications is not in itself justification for sole source.

**Supply/Service being requested:**

QuantiFERON-TB Gold In-Tube— an interferon-release testing system approved for the diagnosis of tuberculosis infection.

**Supplier being requested:**

Cellestis Inc.  
28358 Constellation Road #698  
Valencia, CA 91355  
1-800-519-4627

**Alternative suppliers that can or might be able to provide supply/service:**

No other interferon -release testing system is presently FDA approved.

**Extent of market search conducted:**

FDA approved test is required.  
No other interferon -release testing system is presently FDA approved.

**Unique features of the supply/service being requested from this supplier, which no alternative supplier can provide:**

Cellestis Inc. is the sole source supplier in the United States of the QuantiFERON-TB Gold In-Tube test and other QuantiFERON-TB test products. QuantiFERON-TB Gold In-Tube was approved by the FDA October 12, 2007 as an aid in diagnosing latent Mycobacterium tuberculosis infection and tuberculosis disease. In December 2005, CDC published QuantiFERON-TB GOLD guidelines noting patient management and cost advantages over current TB testing practices.

**Reasons why my department requires these unique features and what benefit will accrue to the county:**

The Tuberculosis Control Department requires a highly specific and sensitive diagnostic test for tuberculosis patient management. The QuantiFERON-TB Gold In-Tube test is a new in-vitro test with significant advantages over the present TB testing practice which is the tuberculin skin test (TST):

1. QuantiFERON-TB Gold In-Tube eliminates false positives due to BCG vaccination and non-tuberculosis mycobacterium. The TST can give a false positive in both situations.
2. QuantiFERON-TB Gold In-Tube results give an objective answer, with no need for an interpretive reading as with the TST.
3. Because the QuantiFERON-TB Gold In-Tube is a blood test (not an in-vivo test as TST) there are no adverse patient reactions or booster effects that may induce false positive response on re-test.
4. The TST requires a second patient visit for evaluation. QuantiFERON-TB Gold In-Tube provides results independent of patient compliance and frees nursing staff from the need to evaluate negative results with no need for a second patient visit.
5. The new "In-Tube" format provides convenient in- field collection. This format enables patient blood to be collected at remote locations. Blood is collected directly into ready to use tubes that are pre-coated with mycobacterial antigens.

**Price Reasonableness:**

QuantiFERON-TB Gold In-Tube should generate a significant cost savings in terms of nursing staff time and the elimination of false positive results. False positives test results may involve follow-up testing that includes chest x-rays and unnecessary TB therapy. Cellestis has offered the County of Riverside a \$2.00 per test discount from their State of California pricing, whereby the County will pay only \$20.00 per test.

**Does moving forward on this product or service further obligate the county to future similar contractual arrangements?**

No, once validated we have no obligation to purchase other Cellestis products.

*Ausand. Harrington* 10/21/08  
 Department Head Signature Date

Purchasing Department Comments:

*Mat R...* 10-17-08  
 Approve Approve with Condition/s Disapprove  
 Purchasing Agent Date