

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

559



FROM: Department of Public Health/Laboratory

SUBMITTAL DATE:  
July 17, 2012

SUBJECT: Approval of the Sole Source purchase of Quantiferon TB In-Tube test kits and reagents from Cellestic Inc.

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 \$35,000 from Cellestis Inc.; and
2. Authorize the County Purchasing Agent to renew the contract annually for a maximum five year contract provided the per-test cost increase does not exceed the CPI.

BACKGROUND: Please see page 2

MC

*Susan O. Harington*

Susan Harington  
Director, Department of Public Health

FINANCIAL  
DATA

Current F.Y. Total Cost:	\$ 35,000	In Current Year Budget:	Yes
Current F.Y. Net County Cost:	\$ 35,000	Budget Adjustment:	No
Annual Net County Cost:	\$ 0.00	For Fiscal Year:	12/13

SOURCE OF FUNDS: Cost of testing will be off-set by revenue charged by the laboratory.

Positions To Be Deleted Per A-30	<input type="checkbox"/>
Requires 4/5 Vote	<input type="checkbox"/>

C.E.O. RECOMMENDATION:

APPROVE

BY: *Debra Cournoyer*  
Debra Cournoyer

County Executive Office Signature

Prev. Agn. Ref.:

District: All

Agenda Number:

ATTACHMENTS FILED  
WITH THE CLERK OF THE BOARD

3.27

FISCAL PROCEDURES APPROVED  
PAUL ANGULO, CPA, AUDITOR-CONTROLLER  
BY *Samuel Wong* 7/5/12  
SAMUEL WONG

Purchasing: *Mark Seiler*  
Mark Seiler, Assistant Director

Dep't Recomm.: ☐ Policy  
Per Exec. Ofc.: ☐ Policy  
☒ Consent  
☒ Policy

**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 discount off their normal State and local government pricing to the County of Riverside. The pricing offered by Cellestis Inc. is fair and reasonable; currently the unit cost per test for Riverside County is \$17.00 which includes shipping costs. The list price is \$22.00 per test.

Date: July 2, 2012

From: Susan Harrington, Director

Department/Agency: Department of Public Health

To: Board of Supervisors

Via: Purchasing Agent

Subject: Sole Source Procurement; Request for QuantiFERON-TB

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.

**1. Supply/Service being requested:**

QuantiFERON-TB Gold In-Tube (interferon gamma release testing system approved for the diagnosis of latent tuberculosis infection) test kits, reagent, and supplies.

**2. Supplier being requested:**

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

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

No other interferon gamma release testing system is presently FDA approved, T-Spot is an approved test for TB but not interferon gamma release type is a 2-step process which has a lower accuracy test rate and requires different instrumentation such as a Flow Cytometer to run. Currently the QuantiFERON is performed on the DSX contracted with Alere North America and approved through June 30, 2013.

**4. Extent of market search conducted:**

Research conducted through the CDC and FDA websites as well as the Laboratory Manager's knowledge of the industry and testing practices for other Public Health Laboratories. The FDA approved test is required, no other interferon gamma release testing system is presently FDA approved.

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

Cellestis Inc. is the sole 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. December 2005, CDC published QuantiFERON-TB GOLD guidelines noting patient management and cost advantages over current TB testing practices.

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

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

- a) 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.
- b) QuantiFERON-TB Gold In-Tube results give an objective answer, with no need for an interpretive reading as with the TST.
- c) 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.
- d) 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.
- e) 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.

**7. Price Reasonableness including purchase price and any ongoing maintenance or ancillary costs from the supplier:**

Cellestis has offered the County of Riverside a generous discount from the list price of \$22.00 per test to \$17.00 per test. QuantiFERON-TB Gold In-Tube should generate a significant cost savings in terms of nursing staff time and elimination of false positive results. False positives test results may involve follow-up testing including chest x-rays and unnecessary TB therapy. Estimated annual amount of \$35,000.00 which the cost will be offset by revenue generated based on approximately an annual quantity of 1,500 test performed at a cost of \$70.00 per test.

**8. Does moving forward on this product or service further obligate the county to future similar contractual arrangements or any ongoing costs affiliated with this sole source? (Maintenance, support, or upgrades, if so, please explain).**

Yes, the Laboratory will require this product for future TB testing.

**9. Period of Performance:**

August 1, 2012 to July 31, 2013, with the renewal option for a maximum of five years, renewable annually, provided the cost increase does not exceed the Consumer Price Index (CPI).

Susan D. Hamilton  
 Department Head Signature

7/3/12  
 Date

Purchasing Department Comments:

Approve

Approve with Condition/s

Disapprove

Not to exceed: \$ 35,000

One time

Annual Amount through 6-30-2017

[Signature]  
 Purchasing Agent

July 3, 2012  
 Date

13-034  
 Approval Number  
 (Reference on Purchasing Documents)