

**JUSTIFICATION AND APPROVAL FOR ALLOWING AWARD OF CONTRACT  
WITHOUT COMPETITION**

*(Section A must be completed by the User Department and then submitted to the Department of Purchasing & Contract Compliance)*

**SECTION A**

**Department:** *Health & Wellness*

**Department Contact:** *Ruby Lewis-Hardy*

**Description of Supplies/Services:** QuantiFERON TB Gold tube testing kits for the Ryan White clients. The TB Gold tube testing kits are needed to provide lab service procedures to the clients.

**Demonstration of Contractor's Unique Qualifications:**

*Fulton County Department of Health and Wellness receives a grant for clients that are HIV positive. Part of the grant is for Ryan White clients to receive the QuantiFERON TB testing. Cellestis is the only company within the United States that sells this test and has exclusive rights to the patented QuantiFERON technology. This patent is licensed from CSIRO (Australia) and is valid in the U.S. until 2011 under US Patent no. 5334504. In addition, 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 and other QuantiFERON test products within the United States (except Puerto Rico and U.S. Virgin Islands).*

*(Section B must be completed by the Department of Purchasing & Contract Compliance)*

**SECTION B**

**MARKET SURVEY**

**Results of Market Survey**

*Include resources researched*

**Date Public Notice posted on website:**

**Date Public Notice closed:**

**REVIEW OF OFFER(S)**

**Were any offers received (Y/N):**

**Number of offers received:**

**Respondents:**

**Date Offers submitted to User Department for review:**

**User Department review and recommendation:**

**Purchasing Agent review and recommendation:** *Include whether a competitive process is being recommended & estimated date of solicitation.*

## CERTIFICATION

Having conducted a good faith review of source availability regarding the materials, goods and or services stipulated herein, subsequent to consultation with the County Manager and the recommendation of the User Department, it has been determined that there is only one source available for the required work, labor or service to be done or the supplies, materials, or equipment to be furnished. Per the Fulton County Code of Ordinances §2-319, Conditions allowing for award of contract without competition.

I, Cecil S. Moore, Director, certify that the facts and representations under my cognizance which are included in this justification and its supporting documentation which form the basis for this justification are complete and accurate.

\_\_\_\_\_  
Cecil S. Moore  
Director

\_\_\_\_\_  
Date

I, Zachary Williams, County Manager, certify that the facts and representations under my cognizance which are included in this justification and its supporting documentation which form the basis for this justification are complete and accurate.

\_\_\_\_\_  
Zachary Williams  
County Manager

\_\_\_\_\_  
Date