Agency Director Approval County Manager's Approval

Typed Name and Title Phone

Signature Date

Revised 03/12/09 (Previous versions are obsolete)

Fulton County Board of Commissioners

Agenda Item Summary

BOC Meeting Date
5/20/2015

Requesting Agency
Health and Wellness

Commission Districts Affected
All Districts

Requested Action (Identify appropriate Action or Motion, purpose, cost, timeframe, etc.)
Request approval of contract - The Department of Health and Wellness Tuberculosis and Syphilis testing in the amount of $34,250 with Gold Standard Diagnostics to provide the ThunderBolt® EIA Automated Platform and reagents needed to conduct tuberculosis and syphilis testing for individuals presenting and referred to the Fulton County Tuberculosis and Sexually Transmitted Disease Clinics upon execution of contract through December 31, 2015 and renewable yearly.

Requirement for Board Action (Cite specific Board policy, statute or code requirement)
In accordance with Fulton County Purchasing Code, sections 1-117 and State of Georgia O.C.G.A §36-10-1, contractual agreements shall be forwarded to the Board of Commissioners for approval. Effective date: Upon BOC approval.

Is this Item Goal Related? (If yes, describe how this action meets the specific Board Focus Area or Goal)
Yes Focus Area, Goal 1: Health and Wellness Services; goal 2: to coordinate health and social services in collaboration with community partners and to provide prevention programs o needy and at risk population that enhance quality of life.

Is this a purchasing item?
No

Summary & Background
The Department of Health and Wellness requests approval of a contract with Gold Standard Diagnostics to provide the ThunderBolt® EIA Automated Platform and reagents needed to conduct tuberculosis and syphilis testing for individuals presenting and referred to the Fulton County Tuberculosis and sexually transmitted disease clinics. This rental agreement is 100% grant funded with no requirement for county matching funds.

This contract is a reagent rental contract/agreement made between the diagnostics company and a laboratory (Fulton County Department of Health and Wellness Laboratory) in which an analyzer (The Thunderbolt) will be placed in a laboratory in exchange for the purchase of reagents. The total amount of the yearly contract will be $34,250 which is the cost of reagent over a one year period. The contract is prorated for the purchase of the reagents for the remainder of this year.

Tuberculosis control is a mandated service of the Department of Health and Wellness. Testing is performed during business hours at the clinic, outreach events, and mass screening events.

Tuberculosis testing is needed to determine if a client has active tuberculosis or latent tuberculosis. Each case of TB prompts an investigation by the Health Department who staffs investigate, treat,
and manage both latent TB infection (LTBI) and active TB disease in county residents. Treatment of active and latent tuberculosis is needed to ensure this disease does not spread in the community or lead to morbidity or death to individuals with the disease.

The Fulton County Sexually Transmitted Disease Clinic screens clients for syphilis in addition to other diseases. Treatment of syphilis leads to decreased incidence in the community, decreases the spread of HIV, and leads to decreased morbidity for individuals and children born to women who are free from the disease.

Fulton county has the highest rate of syphilis in the United States. Syphilis is a sexually transmitted disease that is associated with the spread of HIV. It is a treatable condition that can be diagnosed with a simple laboratory test.

The Thunderbolt machine provides a single hardware solution that can perform laboratory tests for syphilis and tuberculosis QuantiFERON blood tests.

<table>
<thead>
<tr>
<th>Contract &amp; Compliance Information</th>
<th>(Provide Contractor and Subcontractor details.)</th>
</tr>
</thead>
</table>


### Agency Director Approval

<table>
<thead>
<tr>
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Revised 03/12/09 (Previous versions are obsolete)
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<tr>
<td>Total Prime Value</td>
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**Fiscal Impact / Funding Source**<br>(Include projected cost, approved budget amount and account number, source of funds, and any future funding requirements.)

This contract will be 100% grant funded by the Centers for Disease Control and Prevention grant to Fulton County Department of Health and Wellness under Comprehensive High HIV Prevention Programs for Health Departments (High Impact HIV Prevention).

**Exhibits Attached**<br>(Provide copies of originals, number exhibits consecutively, and label all exhibits in the upper right corner.)

**Source of Additional Information**<br>(Type Name, Title, Agency and Phone)

---

**Agency Director Approval**

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**County Manager’s Approval**

Revised 03/12/09 (Previous versions are obsolete)
**Procurement**

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<tr>
<td></td>
<td>Department of Health and Wellness</td>
<td>Dr. Patrice A. Harris</td>
<td>404.613.1205</td>
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**Description:**

**FINANCIAL SUMMARY**

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**KEY CONTRACT TERMS**

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**ROUTING & APPROVALS**

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<td>Finance/Budget Analyst/Grants Admin:</td>
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<td>X</td>
<td>County Manager:</td>
<td>Anderson, Dick</td>
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Packet Page -103-
**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:** Fulton County Department of Health and Wellness (Vendor: Gold Standard Diagnostics).

**Department Contact:** Patrice D. Harris, Director, Health and Wellness; 404-613-1205

**Description of Supplies/Services:** Diagnostics technologies such as EIA, chemiluminescence and multiplexing such as syphilis and QuantiFERON which is blood test that is used to diagnose tuberculosis (primarily latent, or inactive tuberculosis)

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

The category for the basis of award of a contract without competition is single/sole source provider.

As of the date Gold Standard Diagnostics Inc is the only manufacturer of record and sole U.S. supplier of the ThunderBolt® EIA Automated Platform (Catalog # 00300).

The GSD Thunderbolt elisa platform and its operating software has a validated applications to automated both the Qiagen QuantiFERON Gold elisa test kit (QFG TB assay) and the GSD TrepSure Syphilis elisa assay.

And as required by Fulton County laboratory the instrument has been demonstrated by Gold Standard Diagnostics at the laboratory facility.

The Thunderbolt by (GSD) is a walk-away processor of any EIA or Chemiluminescence assay. The ThunderBolt platform will provide laboratory customers with a single hardware solution that can utilize multiple diagnostics technologies such as EIA, chemiluminescence and multiplexing. The inaugural product of the ThunderBolt platform is an EIA (enzyme immunoassay) processor, with a completely open software design capable of programming virtually any EIA test. EIA tests are widely used to detect and quantify substances such as peptides, proteins, antibodies and hormones, and to diagnose diseases and conditions including infections, cancer, metabolic disorders, allergies and autoimmune diseases.

In a single, easily configured run, the flexible ThunderBolt EIA processor can process multiple microtiter plates, while also running up to eight different simultaneous assays. With an onboard reader, the fully automated EIA processor offers a true “walkaway” solution.

*(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, Felicia Strong-Whitaker, Interim 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.

____________________________  ______________________
Felicia Strong-Whitaker    Date
Interim Director, Department of Purchasing

I, Patrick O’Connor, Interim 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.

____________________________  ______________________
Patrick O’Connor    Date
Interim County Manager
James Thompson  
Chief Financial Officer  
Gold Standard Diagnostics  
2851 Spafford Street  
Davis, CA 95618  
(530) 759-8000  
info@gsdx.us

Fulton County Health Department  
ATTN: Ms. Cassandra Marquette  
Phone: (404) 613-2620  
Cassandra.Marquette@fultoncountyga.gov  
99 Jess Hill Jr Drive, SE  
Atlanta, GA 30303

To whom it may concern:

As of the date of this letter, Gold Standard Diagnostics is the manufacturer and sole U.S. supplier of the ThunderBolt® EIA Platform (Catalog # 00300).

The GSD Thunderbolt ELISA Analyzer and its operating software has been programmed to automate both the Qiagen QuantiFERON Gold test kit (QFG TB assay) and the GSD Syphilis IgG ELISA assay. As required by Fulton County labs the instrument has been demonstrated by Gold Standard Diagnostics at the lab facility.

Sincerely,

James Thompson, Chief Financial Officer
REAGENT RENTAL AGREEMENT

This Reagent Rental Agreement (the "Agreement") is made and entered into as of the October 1, 2014 ("Execution Date") by and between Gold Standard Diagnostics, Corp., a Delaware corporation with principal offices at 2851 Spafford Street, Davis, CA. 95618 ("Company"), and Fulton County, Georgia, a political subdivision of the State of Georgia, for the benefit of the Fulton County Health Department ("Customer"), a Clinical Laboratory with principal offices at 99 Jesse Hill Drive S.E. Atlanta, GA. 30303;

WHEREAS, Company is engaged in the manufacture, development and distribution of certain medical diagnostics products; and

WHEREAS, Customer wishes to purchase or utilize certain diagnostic products from Company.

NOW, THEREFORE, in consideration of the mutual covenants hereinafter contained, the parties hereto agree as follows:

1) Equipment

a) Upon execution of this Agreement by all parties, Company agrees to furnish the equipment (the "Equipment") indicated below for use only by Customer during the Term of this Agreement in accordance with the provisions hereof.

| ThunderBolt EIA Robotic Analyzer | Serial # TBD |

b) The Equipment will be supplied by Company and the above Customer shall be free to use such Equipment during the Term of this Agreement only at its premises located at:

99 Jesse Hill Drive SE Atlanta, GA. 30303

provided, however, if Customer desires to move the Equipment to another location, Customer shall obtain Company's prior written consent to such relocation, which consent shall not be unreasonably withheld, conditioned and delayed; and provided further, if Company must be involved in such relocation, Customer shall provide reasonable assistance to Company and shall reimburse Company for any out-of-pocket expenses Company incurs in making such relocation.

c) Customer shall pay for all shipping charges for delivery of the Equipment to Customer and for return of the Equipment to Company.

d) Company shall coordinate and provide all service or repair of the Equipment for a period of twelve (12) months free of charge. Following notification to Company by Customer of a service failure of the Equipment, on-site service shall be provided within 48 hours of the next weekday, Monday through Friday, not including holidays. Customer agrees to purchase a service contract for $5,500 for the second year of the Agreement. If the Agreement is renewed after the Initial Term, Customer may purchase a service contract at a cost of $5,500 per year thereafter.

e) The Customer will be responsible for: (i) any damage to the Equipment caused by the Customer's carelessness, accident, misuse or alteration of the Equipment (ii) any damage to the Equipment as a result of casualty occurring at the Customer's premises, except for any damage to the Equipment that is caused by the negligence or willful misconduct of Company or any of its
employees, agents, representatives or contractors, (iii) any other loss or damage to the Equipment, except for any damage to the Equipment that is caused by the negligence or willful misconduct of Company or any of its employees, agents, representatives or contractors, and (iv) maintenance and cleaning of the Equipment.

f) The Company is and shall remain the owner of all the Equipment provided to the Customer hereunder. Customer shall not permit or suffer any attachment, lien, and encumbrance or security interest to be filed against the Equipment and shall promptly notify Company if any of the foregoing is filed against same, and the Customer shall remove and/or satisfy any attachment, lien, and encumbrance or security interest within a reasonable period. The Customer shall not remove, alter or cover any labels, symbols, serial numbers or any other items, upon or affixed to the Equipment which may be used to identify it as the property of Company.

g) Except for the Company’s obligation to coordinate service or repair covered by the Company’s warranties, if any, Company disclaims all warranties, express or implied including the implied warranties of merchantability and fitness for use. The Company’s obligation to coordinate service or repair is the Customer’s sole remedy for breach of warranty or this Agreement and is in lieu of all possible liability and damages on the part of Company, including, but not limited to, indirect, incidental, or consequential damages whether from personal injury, property damage, loss of business or otherwise on the part of the Customer or third persons relating to the handling, use or performance of the Equipment and services provided hereunder, and Customer agrees that Company’s liability is so limited.

h) The Company is not responsible for any service costs that are the result of: (1) any nonconformity resulting from Customer’s misuse, improper use, neglect, alteration or damage of the Equipment, 2) accident, misuse, neglect, fire, war, power outages or electrical problems that are external to the Equipment or failure to use the Equipment in compliance with published user instructions, (3) acts of God, (4) damage in the relocation or transportation of the Equipment, (5) unauthorized alterations of the Equipment, (6) use of chemicals that are not used for normal operation of the Equipment, or (7) use of third party hardware or software.

i) If the Customer breaches this Agreement, Company, after giving Customer written notice specifying the breach and affords Customer a reasonable opportunity to cure the failure, reserves the right to remove all the Equipment provided hereunder at Customer’s expense and Customer is required to compensate Company the prorated reagent commitment as listed in Exhibit A.

2) Reagents

a) In return for the Equipment provided hereunder, the Customer agrees to purchase from Company during the Term of the Agreement, the Annual Purchase Commitment (APC) of the reagents at the prices indicated on the attached price quote (Exhibit A).

b) After the Initial Term of the Agreement, both parties will evaluate the actual purchase volume of the Customer, against the APC. In the event that the Customer does not meet the total Purchase Commitment, Company will invoice the Customer for the difference between the APC and the actual purchase volume, and Customer agrees to pay the difference within 15 days of the invoice date.

c) Company will provide, at a discount of 50%, all necessary reagents required to validate the performance characteristics of the Equipment and reagents in conformance with CLIA and CAP
requirements. Company, at Company’s expense, will provide technical support and training at Customer’s facility for instrument operation and maintenance.

d) If the Agreement is extended after the Initial Term, Company reserves the right to increase reagent pricing during the Extended Term, but in no event will any reagent pricing increase exceed three percent (3%) annually.

e) All reagents supplied hereunder will conform to the specifications in the reagents’ respective directions for use. In the event that the reagents fail to conform to the specifications in the respective directions for use, Company’s sole obligation shall be to replace the defective reagents with reagents which conform to the specifications in the reagents’ respective directions for use or if such replacement is not possible, then Gold Standard Diagnostics’ liability shall be limited to the cost of said reagents. Should the Company fail to supply reagents as specified under the minimum reagent purchase commitment, as indicated in Exhibit A, Customer shall be relieved of any requirement to purchase that reagent, for such time until such reagent supply is consistently made available to customer plus ninety (90) days. Company makes no other express warranty and disclaims any and all other express or implied warranties including, without limitation, implied warranties of merchantability or fitness of the reagents for any particular purpose or use. The stated limited warranty and remedy are in lieu of all possible liability and damages on the part of Company, including, but not limited to, liability for indirect, incidental or consequential damages, whether from personal injury, property damage, loss of business or otherwise on the part of customer or third persons relating to the handling, use or performance of the reagents, and customer agrees that Company liability is so limited.

3) Commitment Period

The term (the “Initial Term”) of this Agreement is for a twelve month (12) month period beginning upon execution and ending absolutely on December 31, 2014 and shall automatically renew for a consecutive twelve (12) month term. Unless this Agreement is terminated by either party by giving the other party written notice of termination at lease ninety (90) days prior to the end of the Initial Term or renewal period of this Agreement.

4) Terms

Company shall ship the Reagents and Supplies in a manner consistent with general industry practice for these kinds of goods so as to minimize deterioration or damage in transit. All shipments shall be made FOB shipping point, with freight and handling costs prepaid and added to the invoice. Title and risk of loss for the Reagents and Supplies shall pass to Customer at the time of shipment to Customer. Payment terms are net thirty (30) days from the date of invoice. Payment terms are net thirty (30) days from the date of invoice. Invoices not paid within fifteen (15) days of the date specified therefore in this Agreement shall bear interest in an amount equal to the lesser of one and one/half percent (1.5%) per month or the maximum amount legally allowable by law.

5) Repossession

In the event the Customer breaches this Agreement due to non-payment of invoices, Company, after giving Customer written notice of such non-payment and giving Customer ten (10) days from the date of its receipt of such notice to make the payment, may, in addition to any other
remedies it may have in law or in equity, at its own discretion and without further liability whatever, immediately terminate this Agreement upon notice to the Customer, and Company shall thereafter have the right to enter Customer’s premises and take possession and remove all of the Equipment supplied under this Agreement from Customer’s premises without further notice and without need of any legal process, free of any and all claims by Customer for doing so.

6) Force Majeure

Company shall not be liable for any failure to perform its obligations hereunder, due to strikes, fires, explosion, food, water damage, riot, lockout, injunction, interruption of transportation, accidents, government acts or orders, inabilities to obtain equipment or materials at reasonable prices or terms or for other causes beyond its reasonable control, however, should at any time, Company fail to supply reagents as specified under the minimum reagent purchase commitment as indicated in Attachment 1, Customer shall be relieved of any associated minimum purchase requirement for such time until such reagent supply is consistently made available to customer plus ninety (90) days.

7) Governing Law

This Agreement will be governed by, construed and interpreted in accordance with the laws of State of Georgia.

8) Representations

In carrying out this Agreement, Customer shall act as an independent contractor and not as an agent or legal representation of Company. Neither party is authorized to, or shall undertake to, bind the other party in any way, except with the consent of the other party and except where required pursuant to law. This Agreement shall not be deemed to establish a joint venture or partnership between Customer and Company.

9) Product Reimbursement

Company reserves the right to remove products on PRODUCT QUOTE should a Regulatory Authority impose conditions or limitations that cause the Product to no longer be commercially viable. Company will use best efforts to replace product that has been removed from Product Quote with another of equal value.
IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed by their duly authorized representatives as of the date last written below.

Gold Standard Diagnostics, Corp.  Fulton County Health Department

By: ________________________________  By: ________________________________

Name: ______________________________

Title: ______________________________

Date: ______________________________

Name: ______________________________

Title: ______________________________

Date: ______________________________
Exhibit A – Reagents Subject to Annual Purchase Commitment

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Other Terms and Conditions

- GSD will provide the unpacking, installation, training for the Equipment.
- GSD will provide validation services for the kit(s) listed in Exhibit A above.
- Customer’s validation of the Qiagen Quantiferon Gold TB Test on the Equipment shall be the responsibility of Qiagen technical personnel and the Customer.
- Company cannot guarantee the performance, reliability, results or availability of the Qiagen Quantiferon TB Gold assay.