

**BOC Meeting Date**  
10/15/2014**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, 2014 with two (2) renewal options.

**Requirement for Board Action** *(Cite specific Board policy, statute or code requirement)*

O.C.G.A. § 36-10-1 requires all official contracts entered into by the County governing authority with other persons in behalf of the County shall be in writing and entered on its minutes.

**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***(First sentence includes Agency recommendation. Provide an executive summary of the action that gives an overview of the relevant details for the item.)*

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

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

**Agency Director Approval****County Manager's Approval****Typed Name and Title****Phone****Signature****Date**

Continued

decreased morbidity for individuals and children born to women who are free from the disease.

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 control is a mandated service of the Department of Health and Wellness

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 replaces existing testing equipment that could not be repaired and provides a single hardware solution that can perform laboratory tests for syphilis and tuberculosis QuantiFERON blood tests.

Contract & Compliance Information	(Provide Contractor and Subcontractor details.)
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Agency Director Approval		County Manager's Approval
Typed Name and Title	Phone	
Signature	Date	

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

**# 14-0823**

<b>Solicitation Information</b>	<b>NON-MFBE</b>	<b>MBE</b>	<b>FBE</b>	<b>TOTAL</b>
No. Bid Notices Sent:				
No. Bids Received:				
<b>Total Contract Value</b>	.			
<b>Total M/FBE Values</b>	.			
<b>Total Prime Value</b>	.			
<b>Fiscal Impact / Funding Source</b> <i>(Include projected cost, approved budget amount and account number, source of funds, and any future funding requirements.)</i> 461-750-CD3A-1464 Grant Fund, Health and Wellness, Laboratory Supplies				
<b>Exhibits Attached</b> <i>(Provide copies of originals, number exhibits consecutively, and label all exhibits in the upper right corner.)</i> Exhibit#1 – Reagent Rental Agreement				
<b>Source of Additional Information</b> <i>(Type Name, Title, Agency and Phone)</i> Patrice Harris, MD Director, Health and Wellness 404-613-1205				

<b>Agency Director Approval</b>		<b>County Manager's Approval</b>
<b>Typed Name and Title</b>	<b>Phone</b>	
<b>Signature</b>	<b>Date</b>	

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

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**Procurement**

<b>Contract Attached:</b> Yes	<b>Previous Contracts:</b> No		
<b>Solicitation Number:</b> .	<b>Submitting Agency:</b> Department of Health and Wellness	<b>Staff Contact:</b> Dr. Patrice A. Harris, District Health Director	<b>Contact Phone:</b> 404.613.1205

**Description:.****FINANCIAL SUMMARY**

<b>Total Contract Value:</b>	<b>MBE/FBE Participation:</b>
Original Approved Amount: .	Amount: . %: .
Previous Adjustments: .	Amount: . %: .
This Request: \$68,500	Amount: . %: .
TOTAL: \$68,500	Amount: . %: .

**Grant Information Summary:**

Amount Requested: .	<input type="checkbox"/>	Cash
Match Required: .	<input type="checkbox"/>	In-Kind
Start Date: .	<input type="checkbox"/>	Approval to Award
End Date: .	<input type="checkbox"/>	Apply & Accept
Match Account \$: .		

<b>Funding Line 1:</b> 461-750-CD3A-1464.	<b>Funding Line 2:</b> .	<b>Funding Line 3:</b> .	<b>Funding Line 4:</b> .
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**KEY CONTRACT TERMS**

<b>Start Date:</b> 10/15/2014	<b>End Date:</b> 12/31/2014
<b>Cost Adjustment:</b> .	<b>Renewal/Extension Terms:</b> .

**ROUTING & APPROVALS**

(Do not edit below this line)

X	Originating Department:	McKenna, Matthew	Date: 10/1/2014
.	County Attorney:	.	Date: .
.	Purchasing/Contract Compliance:	.	Date: .
X	Finance/Budget Analyst/Grants Admin:	Parker, Jamar	Date: 10/1/2014
.	Grants Management:	.	Date: .
X	County Manager:	O'Connor, Patrick	Date: 10/9/2014

## 2 Year- REAGENT RENTAL AGREEMENT

This Reagent Rental Agreement (the "Agreement") is made and entered into as of the May 9th, 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 Health Department, ("Customer"), a Clinical Laboratory with principal offices at 99 Jesse Hill Drive SE 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 and equipment from the 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.

<b>ThunderBolt EIA Robotic Analyzer</b>	<b>Serial # 13104-198 ( installed )</b>
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- 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:

FULTON COUNTY LAB 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 reagent Agreement. If the Agreement is renewed after the Initial Term, Customer may purchase a service 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 filled against the Equipment and shall promptly notify Company if any of the foregoing is filed against same, and the Customer shall indemnify Company for any loss or damage resulting from any such attachment, lien, and encumbrance or security interest. 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 for a period of twenty-four (24) months, 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 10 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

- a) The term (the "Initial Term") of this Agreement is for twenty four (24) months and shall automatically renew for consecutive twelve month terms ("Extended Term(s)"), unless this Agreement is terminated by either party by giving the other party written notice of termination at least ninety (90) days prior to the end of the Initial Term or any Extended Term 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 which is based on customer PO shipping date of product (test kits) from Davis Ca to Atlanta GA.

### 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, flood, water damage, riot, lockout, injunction, interruption of transportation, accidents, government acts or orders, inability 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 California. In connection with any dispute or controversy arising out, of or relating to this Agreement, both parties consent to the jurisdiction of the United States District Court for California or appropriate State Court.

**8) Certain Indemnifications**

Customer acknowledges that it is responsible for its use of the Equipment provided hereunder, and shall indemnify Company against any and all liability, damage, losses, costs, and expenses (including reasonable attorney fees) which result from Customer's use and from failure to return the equipment as herein provided.

**9) 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.

**10) 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 Diagnostic INC**

**Fulton County Health Department GA**

By: \_\_\_\_\_

By: \_\_\_\_\_

Name: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

Date: \_\_\_\_\_

## Exhibit A – Reagents Subject to Annual Purchase Commitment

<u>Catalog Number</u>	<u>Product Description</u>	<u>Minimum Kits Per Year</u>	<u>US List Price</u>	<u>Contract Price per Kit</u>	<u>12 month Total</u>	<u>Cost per Test</u>
<b><u>TS-96</u></b>	Syphilis 96 Elisa test kit	<u>137</u>	<u>\$395.00</u>	<u>\$250.00</u>	<u>\$34,250.00</u>	<u>\$2.84</u>

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.