CONTRACT #6
RFS # 343.08-00287
Edison # Pending

Department of Health
Laboratory Services

VENDOR:
Hologic, Inc.

STATE OF TENNESSEE
DEPARTMENT OF HEALTH

JOHN J. DREYZEHNER, MD, MPH
COMMISSIONER

BILL HASLAM
GOVERNOR

April 22, 2015

Mr. Jeff Spalding, Executive Director
Fiscal Review Committee
Rachel Jackson Building, 8th Floor
320 Sixth Avenue North
Nashville, TN 37243

and

Mr. Mike Perry, Chief Procurement Officer
Department of General Services
Tennessee Tower, 3rd Floor
Nashville, TN 37243

Dear Director Spalding and CPO Perry:

The Department of Health, Laboratory Services is requesting sole source approval to establish a multi-year (3) contract with 2 options to renew for the purchase of reagent kits and reagent rental equipment to perform testing for Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (GC) using Nucleic Acid Amplification Testing (NAAT). The Hologic Aptima 2 combo is a Food and Drug Administration (FDA) approved NAAT assay for testing human specimens. The NAAT technology is required to meet the standards of the Centers for Disease Control (CDC) for this testing. Hologic is the only company which manufactures a NAAT meeting all the needs of the laboratory.

The features of the Hologic Aptima 2 Combo testing meeting our needs are (1) it has a transport time of 60 days for swabs and 30 days for urine specimens; (2) uses a cap capable of piercing to prevent cross-contamination of samples; (3) does not require pretreatment of urine samples, (4) has automated instrumentation meeting the test needs of the laboratory. The Aptima 2 Combo test is FDA approved of urine, male urethral, endocervical, and self-collected vaginal specimens. The laboratory has also conducted a CDC coordinated verification study to be able to test pharyngeal and rectal specimens. All of these specimen types are needed to diagnose CT and GC infections. The total cost of this contract is $7,012,500.

We appreciate your approval to proceed with this contract and thank you for your consideration.

Sincerely,

John J. Dreyzehner, MD, MPH, FACOEM
Commissioner

5th Floor, Andrew Johnson Tower
710 James Robertson Parkway * Nashville, TN 37243
(615) 741-3111 * www.tn.gov/health

Supplemental Documentation Required for Fiscal Review Committee

*Contact Name:	Jim Gibson	*Contact Phone:	615-262-6303
*Presenter's name(s):	Jim Gibson		
Edison Contract Number: *(if applicable)*		RFS Number: *(if applicable)*	
*Original or Proposed Contract Begin Date:	07/01/15	*Current or Proposed End Date:	06/30/20
Current Request Amendment Number: *(if applicable)*			
Proposed Amendment Effective Date: *(if applicable)*			
*Department Submitting:	Department of Health		
*Division:	Laboratory Services		
*Date Submitted:	04/23/15		
*Submitted Within Sixty (60) days:	Yes		
If not, explain:			
*Contract Vendor Name:	Hologic		
*Current or Proposed Maximum Liability:	4,207,500.00		
*Estimated Total Spend for Commodities:	4,207,500.00		

*Current or Proposed Contract Allocation by Fiscal Year:
(as Shown on Most Current Fully Executed Contract Summary Sheet)

FY:16	FY:17	FY:18	FY:19	FY20	FY
1,402,550.00	1,402,500	1,402,500			

*Current Total Expenditures by Fiscal Year of Contract:
(attach backup documentation from Edison)

FY:	FY:	FY:	FY:	FY	FY
$	$	$	$	$	$

IF Contract Allocation has been greater than Contract Expenditures, please give the reasons and explain where surplus funds were spent:	
IF surplus funds have been carried forward, please give the reasons and provide the authority for the carry forward provision:	
IF Contract Expenditures exceeded Contract Allocation, please give the reasons and explain how funding was acquired to pay the overage:	

Supplemental Documentation Required for Fiscal Review Committee

*Contract Funding Source/Amount:			
State:	100%	Federal:	
Interdepartmental:		*Other*:	
If "*other*" please define:			
If "*interdepartmental*" please define:			

Dates of All Previous Amendments or Revisions: (*if applicable*)	Brief Description of Actions in Previous Amendments or Revisions: (*if applicable*)

Method of Original Award: (*if applicable*)	
*What were the projected costs of the service for the entire term of the contract prior to contract award? How was this cost determined?	$7,012,500.00 Cost was determined by quote submitted by vendor, Hologic.
*List number of other potential vendors who could provide this good or service; efforts to identify other competitive procurement alternatives; and the reason(s) a sole-source contract is in the best interest of the State.	Hologic is the only FDA approved method that target amplification nucleic acid probe test that utilizes target capture for the in vitro qualitative detection and differentiation of ribosomal RNA from Chlamydia trachomatis and/or Neisseria gonorrhoeae to aid in the diagnosis of chlamydial and/or gonococcal urogenital disease.

Special Contract Request

This form should be utilized to facilitate contract and procurement requests that require the Chief Procurement Officer's prior approval and that of the Comptroller of the Treasury, as applicable.
NOT required for a contract with a federal, Tennessee, or Tennessee local government entity or a grant.
Route a completed request, as one file in PDF format, via e-mail attachment sent to: agsprs.agsprs@tn.gov.

APPROVED	APPROVED
CHIEF PROCUREMENT OFFICER DATE	COMPTROLLER OF THE TREASURY DATE

Request Tracking #	34308–HL00000287
1. Contracting Agency	Department of Health, Division of Laboratory Services
2. Type of Contract or Procurement Method	☐ No Cost ☐ Revenue ☒ Sole Source ☐ Proprietary ☐ Competitive Negotiation ☐ Other _____
3. Requestor Contact Information	Paula Gibbs 630 Hart Lane Nashville, TN 37243 615-262-6364
4. Brief Goods or Services Caption	5. Request contract with Hologic for purchase of Aptima Combo 2 Assay Nucleic Acid Amplification Test.

Request Tracking #	34308–HL00000287
6. **Description of the Goods or Services to be Acquired**	**Nucleic Acid Amplification test for the detection of Chlamydia trachomatis and Neisseria gonorrhoeae in clinical patient specimens.** **Aptima Combo 2 for CT/NG provides:** **Targeted Detection of rRNA** • **Biologically more abundant per cell - 10,000 fold more rRNA compared to DNA** • **Removes potential amplification inhibitors** • **Eliminates the need for an internal control** • **Allows multiple sample types to be run simultaneously with zero pre-processing** **Confidence in Testing All Specimen Types** • **Vaginal swab - Clinician or patient-collect** • **Unisex swab - Female endocervical/male urethral** • **Urine - Female or male** **Industry-leading Automation** • **Panther system**
7. **Proposed Contractor**	**Hologic**
8. **Name & Address of the Contractor's principal owner(s)** *– NOT required for a TN state education institution*	**Hologics/Gen-Probe** **10210 Genetic Center Drive** **San Diego, CA 92121**
9. **Proposed Contract Period** *– with ALL options to extend exercised* ***The proposed contract start date shall follow the approval date of this request.***	**60 months**
10. **Office for Information Resources Pre-Approval Endorsement Request** *– information technology (N/A to THDA)*	☒ **Not Applicable** ☐ **Attached**
11. **eHealth Pre-Approval Endorsement Request** *– health-related professional, pharmaceutical, laboratory, or imaging*	☒ **Not Applicable** ☐ **Attached**
12. **Human Resources Pre-Approval Endorsement Request** *– state employee training*	☒ **Not Applicable** ☐ **Attached**
13. **Are these goods or services currently available on a statewide contract? If YES, please explain why the current statewide contract is not being used for this procurement.**	☐ **NO** ☒ **YES, A current contract is in effect with Hologic and items are ordered off of this contract.**
14. **Maximum Contract Cost** *– with ALL options to extend exercised*	**$ 7,012,500 ($1,402,500 annually)**

Request Tracking #	**34308–HL00000287**
15. Was there an initial government estimate? If so, what amount?	☐ NO ☒ YES, $ 7,012,500
16. Cost Determination Used- How did agency arrive at the estimate of expected costs?	**Vendor Quote**
17. Explanation of Fair and Reasonable Price- Explain how agency determined that price is fair and reasonable	**Vendor is sole source for the specifications outlined in this product. Price comparison with other vendors cannot be done. Price supplied by the vendor.**
18. Documentation of Discussions with Contractor- How did agency document discussions with Contractor? Attach documentation to this request as applicable.	**Discussions via email.**
19. Explanation of Need for or requirement placed on the State to acquire the goods or services	**Rapid confirmation of detection of CTGC infection is needed to ensure proper patient follow-up and contact investigations to prevent the spread of the communicable disease.**
20. Proposed contract impact on current State operations	**Capability of in house testing decreases turn-around-time for testing results and provides better service to the citizens of the State of Tennessee.**

Request Tracking #	34308–HL00000287
21. Justification – Specifically explain why the goods or services should be acquired through the procurement method or contract type selected.	**The APTIMA Combo 2 Assay is a target amplification nucleic acid probe test that utilizes target capture for the in vitro qualitative detection and differentiation of ribosomal RNA from Chlamydia trachomatis and/or Neisseria gonorrhoeae to aid in the diagnosis of chlamydial and/or gonococcal urogenital disease using the PANTHER System. On the PANTHER System, the assay may be used to test the following specimens from symptomatic and asymptomatic individuals: clinician-collected endocervical, vaginal and male urethral swab specimens, patient-collected vaginal swab specimens, and urine specimens. Although other companies offer testing platforms for detection of CT and GC, the APTIMA COMBO 2 Assay performed on the PANTHER instrument offers a combination of attributes that are not available from other vendors. These include:** • **FDA approved method from first catch male and female urine, endocervical, urethral and self-collected or clinician collected vaginal swabs.** • **Current FDA cleared NAAT that will detect the lymphogranuloma venerum (LGV) serovars (L1, L2, and L3) the biological LGV variant, and the new variant nvCT of C. trachomatis.** • **No false positive test results determined for Neisseria gonorrhoeae, or cross reactivity with nongonococcal Neisseria species.** • **Pretreatment of a collected specimen in transport not required** • **Provides automated onboard sample barcode scanning during testing.** • **Allows for continuous loading of samples and reagents.** • **Ability to reuse remaining test in reagent kit to eliminate waste** **Hologics is the only company that provides the Aptima COMBO 2 testing reagents. Sole source procurement with a 5 year contract will enable the laboratory to continue to provide this service at the request of the STD program.**

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For No Cost and Revenue Contracts Only	
22. What costs will the State incur as a result of this contract? If any, please explain.	
23. What is the total estimated revenue that the State would receive as a result of this contract?	
24. Could the State also contract with other parties interested in entering substantially the same agreement? Please explain.	☐ NO ☐ YES
25. Summary of State responsibilities under proposed contract	
For Sole Source and Proprietary Procurements Only	
26. Explanation of Need for or requirement placed on the State to acquire the goods or services	STD program personnel requests capability of this testing at the State laboratory to expedite patient diagnosis, contact investigation and treatment. On-site testing helps the laboratory meet CDC testing guidelines.
27. Evidence of Contractor's experience & length of experience providing the goods or services to be procured.	Gen-Probe (purchase by Hologics) has been in business for over 30 years and have specialized in detection of sexually transmitted diseases. Laboratory Services has used their products for more than 15 years without complaints in the quality of results or customer service.
28. Has the contracting agency procured the subject goods or services before? If yes, provide the method used to purchase the goods or services and the name and address of the contractor.	☐ NO ☒ YES, Method: Sole Source – Agency Contract Name/Address: Hologics/Gen-Probe 10210 Genetic Center Drive San Diego, CA 92121
29. Contractor selection process and efforts to identify reasonable, competitive, procurement alternatives	Sole Source Vender
Signature Required for all Special Contract Requests	

Request Tracking #	34308–HL00000287

Agency Head Signature and Date – *MUST be signed by the ACTUAL agency head as detailed on the current Signature Certification. Signature by an authorized signatory is acceptable only in documented circumstances*

Signature:

Date:

Terms and Conditions

Event Number: 34301-XXXX

Standard Terms and Conditions

Instructions to Bidders:

1. Read the entire bid, including all terms and conditions and specifications.

2. If submitting the bid by mail: All bid prices must be typed or written in ink on the Line Details portion of the Invitation to Bid (ITB); any corrections, erasures or other forms of alteration to unit prices must be initialed by the bidder.

3. If submitting the bid by mail, the bid must be manually signed in ink; failure to do so will cause rejection of your bid. If submitting the bid on-line, your electronic signature constitutes having signed the bid.

4. Bid prices shall include delivery of all items F.O.B. destination or as otherwise specified.

5. Address all inquiries and correspondence to the Purchasing Agent indicated in the Invitation to Bid.

6. I (we) agree to strictly abide by all the statutes and terms contained in the rules of the Department of General Services, Central Procurement Office which are by reference made a part hereof, in addition to the Standard and Special Terms & Conditions, and Specifications embodied in this Invitation to Bid.

7. IMPORTANT: By submitting the bid, the Bidder certifies compliance with the above and further certifies that this bid is made without collusion or fraud.

8. State statutes require that all bidders be registered prior to the issuance of a contract or a purchase order. Vendors/Bidders can register online at the State of Tennessee Supplier Portal: https://supplier.edison.tn.gov.

9. I (We) propose to furnish and deliver any and all of the supplies, services, and/or other commodities named in the Invitation to Bid, and for which I (we) have set prices in my (our) offering.

10. It is understood and agreed that this bid, when certified by authorized signature, shall constitute an offer, which when accepted in writing by the Department of General Services, Central Procurement Office, and subject to the terms and conditions of such acceptance, will constitute a valid binding contract between the State of Tennessee and the Vendor/Contractor (bidder) submitting such offering.

11. By my (our) written signature on this bid I (we) guarantee and certify that all items included in the bid meet or exceed any and all State specifications covering such items. I (We) further agree, if awarded a contract or purchase order as a result of this bid, to deliver such commodities, service or merchandise which meet or exceed the specifications.

12. It is understood and agreed that no contract may be assigned, sublet, or transferred without the written consent of the Central Procurement Office.

13. The inclusion in any response of a limitation of remedies or liabilities clause may be cause for rejection, unless otherwise specified in this solicitation or in accordance with the provisions of *Tennessee Code Annotated* § 12-3-701 or Central Procurement Office Rules, policies or procedures.

14. All bidders have the right to inspect the bid file, prior to award, upon completion of the evaluation by the Central Procurement Office. Interested bidders should contact the Purchasing Agent following the bid opening date or once the file is open for the seven (7) day inspection period. A "File Open for Inspection" letter will be sent to all bidders detailing the bidder(s) recommended for award and the evaluated award amount(s). Upon request, a reasonable opportunity to inspect the bid file will be provided to the bidder. If there is no request to inspect the bid file by the end of the seven (7) day inspection period, the Purchasing Agent will proceed with the award.

15. Protest by Vendor: Pursuant to Tenn. Code Ann.§ 4-56-103, any actual proposer may protest. Please refer to the Central Procurement Office's website to obtain a copy of the protest procedures and protest bond requirements or contact the sourcing analyst or category specialist at 615-741-1035. The website for the Central Procurement Office is as follows: http://tn.gov/generalserv/cpo/for_bidders.html

16. Bid Mailing Instructions: Each individual bid proposal must be returned in a separate envelope package or container and must be properly labeled on the outside referencing the applicable event number and the bid opening date. Bids should be mailed in a properly labeled sealed envelope to the following address:

Department of General Services, Central Procurement Office
Attn: Bidder Services
3rd Floor, William R Snodgrass, Tennessee Tower
312 Rosa L. Parks Avenue
Nashville, TN 37243-1102

17. Subject to paragraph 13, the Contractor agrees to indemnify and hold harmless the State of Tennessee as well as its officers, agents, and employees from and against any and all claims, liabilities, losses, and causes of action which may arise, accrue, or result to any person, firm, corporation, or other entity which may be injured or damaged as a result of acts, omissions, or negligence on the part of the Contractor, its employees, or any person acting for or on its or their behalf relating to this Contract. The Contractor further agrees it shall be liable for the reasonable cost of attorneys for the State in the event such service is necessitated to enforce the terms of this Contract or otherwise enforce the obligations of the Contractor to the State.

In the event of any such suit or claim, the Contractor shall give the State immediate notice thereof and shall provide all assistance required by the State in the State's defense. The State shall give the Contractor written notice of any such claim or suit, and the Contractor shall have full right and obligation to conduct the Contractor's own defense thereof. Nothing contained herein shall be deemed to accord to the Contractor, through its attorney(s), the right to represent the State of Tennessee in any legal matter, such rights being governed by Tennessee Code Annotated, Section 8-6-106

18. Contracts are entered into solely for the convenience of the State of Tennessee. The vendor/contractor understands and agrees that the State of Tennessee, as a signatory party to a contract, is solely responsible for its performance, and that the officers and employees of the Department of General Services, Central Procurement Office, act exclusively as agents of the State for the award, consummation, and administration of contracts and are not personally liable for any performance or nonperformance by the State.

19. A bid must be received in the Central Procurement Office on or before the date and hour designated for the bid opening or the bid will be rejected.

20. The Central Procurement Office may reject any or all bids. Action to reject all bids shall be taken only for unreasonably high prices, errors in the Invitation to Bid (ITB), cessation of need, unavailability of funds, or any other reason approved by the Procurement Commission. The Procurement Commission has

authorized rejection of all bids for failure to secure adequate competition. If an ITB is to be re-advertised, all prior bids shall remain closed to inspection until the evaluation of the re-advertisement is complete.

21. All present and former employees or officials of the State are referred to Tennessee Code Annotated 12-4-103.

22. Any individuals with disabilities who wish to participate in public meetings such as a scheduled pre-bid conference or other scheduled function should contact the Central Procurement Office to discuss any auxiliary aids or services needed to facilitate such participation. Such contact may be in person, by writing, telephonically, or otherwise, and should be made no less than ten (10) days prior to the scheduled event, to allow time for the Central Procurement Office to provide such aid or service.

23. No person on the grounds of handicap or disability, age, race, color, religion, sex, national origin, or any other classification protected by Federal and/or Tennessee State Constitutional and/or statutory law shall be excluded from participation in, or denied benefits of, or be otherwise subjected to discrimination in the performance of the Contract or in the employment practices of the vendor/contractor. The vendor/contractor shall, upon request, show proof of such non-discrimination, and shall post in conspicuous places, available to employees and applicants, notices of non-discrimination.

24. TAXES: Purchases of goods by the State of Tennessee are exempt from Tennessee sales and use tax pursuant to Tenn. Code Ann. 67-6-329(a) (4), and the state is generally exempt from Federal excise tax. Contractors are subject to Tennessee sales and use tax on all materials and supplies used in the performance of a contract, whether such materials and supplies are purchased by the contractor, produced by the contractor, or provided to the contractor by the State, pursuant to Tenn. Code Ann. 67-6-209. The contractor agrees to pay all taxes incurred in the performance of an awarded contract.

State agencies which procure products for the purpose of resale shall register with the Department of Revenue. Upon registration the agency will issue resale certificates to the successful contractor(s) for products procured for resale. The agency is responsible for the collection of the appropriate sales or use tax when the product is sold.

25. Exceptions to terms and conditions and/or those proposed by the bidder which may vary from the invitation to bid may render the bid unresponsive and subject the bid to rejection.

26. Unless otherwise stated, all goods called for by a purchase order must be tendered in a single delivery in compliance with the delivery time specified and payment is due only on such tender. Partial shipments and/or back orders will only be accepted with receiving agency's prior authorization.

27. All products, materials, supplies and equipment offered and furnished must be new, of current manufacturer production, and must have been formally announced by the manufacturer as being commercially available as of the date of the bid opening, unless otherwise stated in this event.

28. Manufacturers of chemical products which are the subject of purchase contracts for the State of Tennessee shall list and maintain a material safety data sheet (MSDS) for such chemical products on the national MSDS search repository or on the manufacturer's website so that such information can be accessed by means of the Internet. A site operated by or on behalf of the manufacturer or a relevant trade association is acceptable so long as the information is freely accessible to the public. In lieu of posting a MSDS on MSDSSEARCH, a bidder shall include the manufacturer's universal resource locator (URL) for its MSDS in the event. For purposes of this MSDS requirement, the Department of General Services recognizes the following URL for national MSDS search repository:MSDS-SEARCH, which can be accessed on the internet at: http://www.msdssearch.com.

29. Conflict of Interest: The State may not consider a solicitation response from an individual who is, or within the past six (6) months has been, a state employee. For purposes of this solicitation, an individual shall be considered to be a "state employee" and prohibited from submitting a response to this solicitation for six (6) months after such time as all compensation for salary, termination pay, and annual leave has

been paid to such state employee. A contract with or a solicitation response from a company, corporation, or any other contracting entity in which a controlling interest is held by a state employee shall be considered to be a contract with or a solicitation response from a state employee as though the state employee were submitting a response or entering a contract on his or her behalf. Notwithstanding the foregoing, a contract with or a solicitation response from a company, corporation, or any other contracting entity that employs an individual who does not own a controlling interest in such entity and who is, or within the past six months has been, a state employee shall not be considered a contract with or a solicitation response from a state employee and shall not constitute a prohibited conflict of interest.

30. Governing Law. This Contract shall be governed by and construed in accordance with the laws of the State of Tennessee. The contractor agrees that it will be subject to the exclusive jurisdiction of the courts of Tennessee in actions that may arise under this contract. The Contractor acknowledges and agrees that any rights or claims against the State of Tennessee or its employees hereunder, and any remedies arising therefrom, shall be subject to and limited to those rights and remedies, if any, available under Tennessee Code Annotated, Section 9-8-101 through 9-8-407.

31. State and Federal Compliance: The contractor shall comply with all applicable state and federal laws and regulations in the performance of this contract.

32. Professional Licensure and Department of Revenue Registration: All persons, agencies, firms, or other entities that provide legal or financial opinions, which a Proposer provides for consideration and evaluation by the State as a part of a proposal in response to this solicitation, shall be properly licensed to render such opinions. Before the Contract resulting from this solicitation is signed, the apparent successful Proposer (and Proposer employees and subcontractors, as applicable) must hold all necessary, appropriate business and professional licenses to provide service as required. The State may require any Proposer to submit evidence of proper licensure. Before the Contract resulting from this solicitation is signed, the apparent successful Proposer must be registered with the Department of Revenue for the collection of Tennessee sales and use tax. The State shall not award a contract unless the Proposer provides proof of such registration. The foregoing is a mandatory requirement of an award of a contract pursuant to this solicitation. For purposes of this registration requirement, the Department of Revenue may be contacted at: TN.Revenue@tn.gov.

33. Prohibition of Illegal Immigrants: The requirements of State of Tennessee's Public Acts, 2006, Chapter Number 878 and Executive Order 41 addressing the use of Illegal Immigrants in the performance of any contract to supply goods or services to the State of Tennessee, shall be a material provision of this contract, a breach of which shall be grounds for monetary and other penalties, up to and including termination of this contract.

As required by Public Acts, 2006, Chapter Number 878, no person may enter into a contract to supply goods or services to the State without first attesting in writing that the person will not knowingly utilize the services of Illegal Immigrants in the performance of this contract, and will not knowingly utilize the services of any subcontractor who will utilize the services of Illegal Immigrants in the performance of this contract. For purposes of this contract, "Illegal Immigrant" shall be defined as any person who is not either a United States citizen, a lawful permanent resident, or a person whose physical presence in the United States is authorized or allowed by the department of homeland security and who, under federal immigration laws and/or regulations, is authorized to be employed in the U.S. or is otherwise authorized to provide services under the contract. The contractor hereby attests, certifies, warrants, and assures that it shall comply with this term and condition for the entire contract period.

The contractor understands and agrees that failure to comply with this section will be subject to the sanctions of Public Chapter 878 of 2006 for acts or omissions occurring after its effective date. This law requires the Commissioner of Finance and Administration to prohibit a contractor from contracting with, or submitting an offer, proposal, or bid to contract with the State of Tennessee to supply goods or services for a year after a contractor is discovered to have knowingly used the services of illegal immigrants during the performance of this contract. The contractor may appeal the imposition of the one-year prohibition by utilizing an appeals process established by the Commissioner of Finance and Administration.

As per Executive Order 41, the contractor shall be required to submit semi-annual Attestation Forms and obtain a signed Attestation Form from any subcontractor prior to the use of the subcontractor and semi-annually thereafter during the contract period. The records shall be subject to review and random inspection at any reasonable time upon reasonable notice by the State. Records shall include but are not limited to the following:

Documentation on contractors' employees and subcontractor personnel working on this contract showing that they are legal to work in the United States and payroll records.
Signed and dated Attestation Forms for your company that have been submitted to the Central Procurement Office and Attestation Forms obtained from subcontractor(s).

Note: The contractor shall be required to obtain prior approval to subcontract from the Central Procurement Office.

By authorized signature on this Invitation to Bid the contractor constitutes signing the Attestation Form for the initial six (6) months of the contract period. The contractor shall be required to submit signed Attestation Forms on a semi-annual basis from the start date of the contract period through to its completion date to the Central Procurement Office. Such attestations shall be maintained by the contractor in a permanent file on the vendor premises and made available to State officials upon request. The State of Tennessee provides an "approved Attestation Form" to support the reaffirmation process. The form can be accessed and printed from the internet at http://tn.gov/generalserv/cpo/for_bidders.html

34. Modifications and Amendments: This Contract may be modified only by a written amendment signed by all parties hereto and approved by both the officials who approved the base contract and, depending upon the specifics of the contract as amended, any additional officials required by Tennessee laws and regulations (said officials may include, but are not limited to, the Chief Procurement Officer, the Commissioner of Human Resources, and the Comptroller of the Treasury).

35. Records: The Contractor shall maintain documentation for all charges under this Contract. The books, records, and documents of the Contractor, for work performed or money received under this Contract, shall be maintained for a period of five (5) full years from the date of the final payment and shall be subject to audit at any reasonable time and upon reasonable notice by the State, the Comptroller of the Treasury, or their duly appointed representatives. The financial statements shall be prepared in accordance with generally accepted accounting principles.

36. Monitoring: The Contractor's activities conducted and records maintained pursuant to this Contract shall be subject to monitoring and evaluation by the State, the Comptroller of the Treasury, or their duly appointed representatives.

37. HIPAA Compliance: The State and Contractor shall comply with obligations under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Health Information Technology for Economic and Clinical Health (HITECH) Act and any other relevant laws and regulations regarding privacy (collectively the "Privacy Rules").

a. Contractor warrants to the State that it is familiar with the requirements of the Privacy Rules, and will comply with all applicable requirements in the course of this Contract.
b. Contractor warrants that it will cooperate with the State, including cooperation and coordination with State privacy officials and other compliance officers required by the Privacy Rules, in the course of performance of the Contract so that both parties will be in compliance with the Privacy Rules.
c. The State and the Contractor will sign documents, including but not limited to business associate agreements, as required by the Privacy Rules and that are reasonably necessary to keep the State and Contractor in compliance with the Privacy Rules. This

provision shall not apply if information received or delivered by the parties under this Contract is NOT "protected health information" as defined by the Privacy Rules, or if the Privacy Rules permit the parties to receive or deliver such information without entering into a business associate agreement or signing another such document.

d. The Contractor will indemnify the State and hold it harmless for any violation by the Contractor or its subcontractors of the Privacy Rules. This includes the costs of responding to a breach of protected health information, the costs of responding to a government enforcement action related to the breach, and any fines, penalties, or damages paid by the State because of the violation.

DRAFT

Special Terms and Conditions

1. F.O.B. Destination (Agency Term Contract)

F.O.B. Point:

Agency Name: Department of Health
Address:
630 Hart Lane
Nashville, TN 37243

2. Term of Contract - Multi-Year

Total Number of Years if all Options are Exercised: 5
Initial Contract Term: Three (3) years with two (2) One-year Options to Renew

Start Date:	**July 01, 2015**
Initial End Date:	**June 30, 2018**
Final End Date:	**June 30, 2020**

The anticipated effective (start) date and expiration (end) dates of the contract are shown above. If award has not been made by the anticipated effective date, then the contract shall become effective upon the date the bid is accepted and contract awarded by the State, as indicated by the purchasing agent's signature on the contract notice of award (note: the change of effective date may not result in a change of the anticipated expiration date.)

RENEWAL OPTIONS: This contract may be renewed upon satisfactory completion of the initial contract term. The State reserves the right to execute up to the number of renewal options listed above annually under the same terms and conditions for a period not to exceed 12 months each by the State. It is mutually understood and agreed that the State's commitment is limited to a base term contract, not to exceed twelve (12) months, which is subject to renewal annually at the State's sole option.

It is understood and agreed that the State reserves the right to extend the term contract period resulting from this solicitation an additional period of time, not to exceed 180 days beyond the normal expiration date of such contract, upon mutual written agreement by both parties, under the same terms and conditions. Provided, however, in no event shall the maximum term of a contract exceed a total of sixty (60) months.

3. Volume, Term Contract

The total purchase of any individual item on the contract is not known. The Central Procurement Office has attempted to give an accurate estimate of purchases for each line item from the current contract period and projected estimates for the new contract period. The Central Procurement Office does not guarantee that the state will buy any or all estimated amounts of any specified item or any total amount.

Estimated Funding New Contract Period $7,012,500.00 ($1,402,500 annually)

The vendor/contractor will only be paid for services rendered hereunder pursuant to purchase order releases issued to contractor from the state. The vendor/contractor is not entitled to be paid the maximum liability for any one year under the contract or any extensions of the contract for product or service not requested by the state. Maximum liability represents available funds for payment to contractor and does not guarantee payment of any such funds to the vendor/ contractor per year under this contract and the state may not request any product or service at all from contractor during any one year period.

4. Bids Requested on Standard State Specifications for Products and/or Services

Unit price bids are requested on products or services that equal or exceed (unless specifications limit the dimensions or brand(s)/model(s) of products to be bid). The absence of detailed specifications or the omission of detail description shall be recognized as meaning that only the best commercial practices are to prevail and that only first quality materials and workmanship are to be used. All interpretations of specifications shall be made from this statement. It is understood that the specifications or references to available specifications shall be sufficient to make the terms of such specifications binding on the vendor/contractor. Bidders must submit for bid evaluation applicable cuts, sketches, descriptive literature, and technical specifications covering the product offered, when applicable. Reference to literature submitted previously will not satisfy this requirement.

Bids requested on architect/engineer/designer specifications, if applicable. Bids are requested per architect/ engineer/designer's specification attached. Bids are to be lump sum and/or unit prices as shown on the price sheet. Any errors or omissions in plans or specifications shall be resolved prior to submission of a bid. Submission of a bid shall constitute agreement and compliance with such specifications and plans. All shop drawings and product sheets required by specifications shall be submitted to architect/engineer/designer prior to fabrication and/or installation.

5. Substitution

Substitution of one or more goods, brands or manufacturers after the contract is awarded is expressly prohibited unless approved in writing by the State. The State may, at its discretion, require the contractor to provide one or more substitute goods of equal quality, subject to the approval by the State, for the same price and on the same delivery terms, if one or more goods for which the contract was awarded becomes unavailable to the contractor.

6. Debarment and Suspension

The Contractor certifies, to the best of its knowledge and belief, that it, its current and future principals, its current and future subcontractors and their principals:

a. are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by any federal or state department or agency;

b. have not within a three (3) year period preceding this Contract been convicted of, or had a civil judgment rendered against them from commission of fraud, or a criminal offence in connection with obtaining, attempting to obtain, or performing a public (federal, state, or local) transaction or grant under a public transaction; violation of federal or state antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification, or destruction of records, making false statements, or receiving stolen property;

c. are not presently indicted or otherwise criminally or civilly charged by a government entity (federal, state, or local) with commission of any of the offenses detailed in section b. of this certification; and

d. have not within a three (3) year period preceding this Contract had one or more public transactions (federal, state, or local) terminated for cause or default.

The Contractor shall provide immediate written notice to the State if at any time it learns that there was an earlier failure to disclose information or that due to changed circumstances, its principals or the principals of its subcontractors are excluded or disqualified.

7. Bid Offer Expiration

Enter the expiration date of your bid offer in the space provided on this Invitation to Bid. A minimum period of thirty (30) days from the bid closing date is requested. The state shall have sixty (60) days to accept the bid if a minimum period is not stated.

8. Delivery Time (Days)

All items must be delivered within approximately 30 days after receipt of a purchase order (ARO).

9. Freight F.O.B. State Agency (Dock)

All quotations shall be F.O.B. destination. The term F.O.B. shall mean delivered and unloaded onto the receiving dock of the agency listed, with all charges for transportation and unloading prepaid by the vendor/contractor.

10. Fixed Bid Price for Contract Period (No Price Increase Allowed)

Bid prices must be fixed for the term of the contract, except the state shall be advised of and receive the benefit of any price decrease in excess of five (5) percent automatically. The vendor/contractor must provide written price reduction information within ten (10) days of its effective date.

11. Bidder's Qualification

Bidders must, upon request of the state, furnish satisfactory evidence of their ability to furnish products or services in accordance with the terms and conditions and specifications. The Assistant Commissioner, Department of General Services, Central Procurement Office, reserves the right to make the final determination as to a bidder's ability to perform.

12. Inspection/Facilities

The Central Procurement Office may inspect the facilities of any bidder or may require additional information regarding a bidder's ability to perform the proposed contract. Bids may be rejected for lack of apparent ability to perform the proposed contract.

13. Inspection of Materials, Equipment and Products

All materials, equipment, and products are subject to inspection and testing. Items that do not meet specifications will be rejected. Failure to reject upon receipt does not relieve the vendor/contractor of liability. When subsequent tests after receipt are conducted and when such tests reveal damage or failure to meet specifications, the state may seek damages regardless of whether a part or all of the merchandise has been consumed.

14. Department of Revenue Registration

The contractor shall be registered with the Department of Revenue for the collection of Tennessee sales and use tax. This registration requirement is a material requirement of this Contract.

15. Bid Rejection

The Central Procurement Office reserves the right to reject any bid that contains prices for individual items or services that are inconsistent or unrealistic when compared to other prices in the same or other bids, if such action would be in the best interest of the state.

Errors: Each correction made by the bidder on the bid response must be initialed in ink by each correction. No corrections will be made in pencil. No bid or line item shall be altered or amended after the bid opening. In the case of errors in the extension price, the unit price will govern. Failure to comply with the above may be cause for rejection of part or the entire bid.

16. Single Award

A single contract for all line items will be awarded to the lowest responsive and responsible bidder whose bid meets the requirements and criteria set forth in the Invitation to Bid. Prices shall be calculated as follows: The bidders unit bid price shall be multiplied by the line item quantity to obtain the line item total. If more than one line item is included in the bid document, each line item total shall be added together for a total price for all line items bid. The bidder must bid all line items to be considered for an award.

17. Award Criteria

An award shall be made to the lowest responsive and responsible bidder considering the following:

Ability to Perform

Conformity to Specifications
Lowest Composite Score

18. State Contract Administrator

Questions or problems arising from bid procedures or subsequent order and delivery procedures should be directed to:

State of Tennessee
Department of General Services, Central Procurement Office
3rd Floor, William R. Snodgrass, Tennessee Tower
312 Rosa L. Parks Avenue
Nashville, TN 37243-1102
Attn: Karen Olive
Phone: 615-253-5686

19. Negotiations

The State may elect to negotiate by requesting revised Cost Proposals from apparently responsive and responsible respondents. However, the State reserves the right to award a contract on the basis of initial responses received. Therefore, each response should contain the respondent's best terms from a price and technical standpoint. The State reserves the right to conduct multiple negotiation rounds. If the State exercises its right to enter into negotiations, it may identify areas of a response that may require further clarification or areas in which it is apparent that there may have been miscommunications or misunderstandings as to the State's specifications and/or requirements. The State may seek to clarify those identified issues during negotiations. All responsive respondents will be given equivalent information with respect to cost negotiations. All cost negotiations will be documented for the procurement file. Additionally, the State may conduct target pricing and other price or service level negotiations. Target pricing may be based on considerations such as current pricing, market considerations, benchmarks, budget availability, or other method that does not reveal individual respondant pricing. During target price negotiations respondents are not obligated to meet or beat target prices, but will not be allowed to increase prices. All communications, clarifications and negotiations shall be conducted in a manner that supports fairness in response improvement. Note that each clarification sought by the State may be unique to an individual respondent.

20. Subcontracting

The Contractor shall not assign this Contract or enter into a subcontract for any of the goods or services provided under this Contract without obtaining the prior written approval of the Central Procurement Office. Notwithstanding any use of approved subcontractors, the Contractor shall be the prime contractor and shall be responsible for all work provided.

21. Purchase Order Releases (Agency Term Contract)

Orders for products or services that are included on agency term contracts shall be prepared by agencies on Departmental Purchase Release Orders and forwarded to the vendor/contractor. These purchase orders, when received by the vendor/ contractor, serve as authorization for shipment of product(s) or start of service.

Billing Instructions:

The vendor/contractor shall invoice the state only after product has been received by the user agency or upon completion of the service described in the purchase order/contract, unless otherwise authorized in writing by the user agency and as required below prior to any payment.

The contractor shall submit an invoice, with all necessary supporting documentation, to the state agency billing address. Such invoice shall clearly and accurately detail the following required information:

1. Invoice/reference number; (assigned by the contractor);
2. Invoice date;
3. Contract and/or purchase order number; (assigned by the state);
4. Account name;
5. Procuring state agency and division name;
6. Account/customer number (uniquely assigned by the vendor/contractor);
7. To the above-referenced account name;
8. Contractor name;
9. Contractor Identification Number; (as referenced in the contract);
10. Contractor contact (name, phone, and/or fax for the person to contact with billing questions);
11. Contractor remittance address;
12. Description of delivered product(s) or service; and
13. Total amount due for delivered product(s) or service.

The contractor understands and agrees that the invoice shall;

· Include only charges for service described in contract or Purchase Order and in accordance with payment terms and conditions set forth in the contract or purchase order;
· Not include any future work but will only be submitted for completed service, unless otherwise authorized in writing by the user agency; and
· not include sales tax or shipping charges (unless otherwise stipulated in the contract or purchase order).

Payment: The contractor agrees that timeframe for payment (and any discounts) begins when the state is in receipt of a correct invoice meeting the minimum requirements above. It shall be the responsibility of the "bill to" agency to make payment in accordance with the Prompt Payment Act of 1985. Any questions concerning payment should be addressed to the "bill to" agency and not to the Central Procurement Office.

22. Contract Cancellation

Termination for Convenience: The State may terminate this contract without cause. Said termination shall not be deemed a breach of contract by the State. The State shall give the vendor/contractor at least ninety (90) days written notice before the effective cancellation date.

The vendor/contractor shall be entitled to receive compensation for product(s) shipped or services satisfactorily completed as of the cancellation date, but in no event shall the state be liable to the vendor/contractor for compensation for any product(s) or services which have not been rendered.

Upon such termination, the vendor/contractor shall have no right to any actual general, special, incidental, consequential, or any other claims whatsoever of any description or amount.

Termination for Cause: If the vendor/contractor fails to fulfill its obligations under this contract in a timely or proper manner, or if the vendor/contractor violates any terms of this contract, the State shall have the right to immediately terminate the contract upon written notice of intent to cancel. The State shall have the right to withhold payment in excess of fair compensation for completed services. Notwithstanding the above, the contractor shall not be relieved of liability to the State for damages sustained by virtue of any breach of this contract by the contractor.

At the end of any fiscal year any contract may be canceled by the state without notice, in the event that funds to support the contract become unavailable.

The vendor/contractor will be required to honor all purchase orders that were prepared and dated prior to the date of the termination, if received by the vendor/contractor within a period of thirty (30) days following the date of cancellation.

23. Subcontracting: Responsibilities and Liabilities, Bond Required if Subcontracting

Based on Tennessee Code Annotated 12-4-201, the vendor/contractor shall not enter into any subcontract for services, prior to or following award, without the written consent of the Central Procurement Office. It is also understood and agreed that no contract may be assigned, sublet, or transferred without the written consent of the Central Procurement Office. The awarded vendor/contractor is responsible for work, service, performance, injuries of employees and payment to the subcontractor.

The subcontractor shall be required to register with Central Procurement Office and provide proof of insurance in accordance with the insurance term and condition, if insurance is required.

All anticipated or actual costs incurred for subcontracting must be included in the bid price per line item. The vendor/contractor can only invoice for actual bid prices per line item; regardless of how much it has agreed to pay the subcontractor.

The successful bidder(s) will be required to furnish a Labor and Material Surety Bond issued by a surety company licensed to do business in the State of Tennessee in the amount of twenty-five (25) % of the total contract amount. The Labor and Material Surety Bond shall be issued by a surety company licensed to do business in the State of Tennessee or an Irrevocable Letter of Credit from a state or national bank or state or federal savings and loan association having its principal office in Tennessee; or any state or national bank or state or federal savings and loan association that has its principal office outside this state and that maintains one (1) or more branches in this state which are authorized to accept federally insured deposits may be accepted by the Central Procurement Office in lieu of a performance bond. The terms and conditions of any letter of credit shall be subject to the approval of the public official named in the contract. The form of such letter of credit shall be provided by the bank or savings and loan association and may be based on either the uniform commercial code, Tennessee Code Annotated, Title 47, Chapter 5, or the ICC Uniform Customs and Practice for Documentary Credits (UPC 500). All letters of credit shall be accompanied by an authorization of the contractor to deliver retained funds to the bank issuing the letter.

The Labor and Material Surety Bond or Irrevocable Letter of Credit shall be furnished to the Central Procurement Office within ten (10) business days after the request. The Labor and Material Surety Bond or Irrevocable Letter of Credit will insure that the contractor will pay for all labor and materials used by the contractor, or any immediate or remote subcontractor under the contractor, in such contract, in lawful money of the United States.

In the event that the Bidder does not indicate that they would be subcontracting and therefore no bond was received, the state reserves the right to request a Labor and Material Surety Bond from the vendor/contractor in the event that a subcontractor submits a claim against the vendor/contractor's surety bond to the Central Procurement Office due to non-payment. If requested, the vendor/contractor will be required to submit a Labor and Material Surety Bond in the amount specified in the request letter within ten (10) business days.

24. Specifications Govern Over Brand Names Listed

The acceptable brands and model numbers are believed to meet all written specifications; however, if an error exists, the specifications will govern.

STATE OF TENNESSEE
DEPARTMENT OF GENERAL SERVICES
CENTRAL PROCUREMENT OFFICE

INVITATION TO BID
EFFORTS TO ACHIEVE DIVERSITY BUSINESS ENTERPRISE PARTICIPATION

The Governor's Office of Diversity Business Enterprise (Go-DBE) is the state's central point of contact to attract and assist minority-owned, woman-owned, Tennessee service-disabled veteran owned, and small business enterprises interested in competing in the State of Tennessee's procurement and contracting activities. These diversity business enterprises are defined as follows:

Minority Business Enterprise (MBE) and Woman Business Enterprise (WBE)
Businesses that are a continuing, independent, for profit business which performs a commercially useful function, and is at least fifty-one percent (51%) owned and controlled by one (1) or more individuals in the minority or woman category who were impeded from normal entry into the economic mainstream because of past practices of discrimination based on race, ethnic background, or gender.

Service-Disabled Veteran Business Enterprise (SDVBE)
"Tennessee service disabled veteran owned business" means a service-disabled veteran owned business that is a continuing, independent, for profit business located in the state of Tennessee that performs a commercially useful function with at least a twenty percent (20%) disability that is service-connected meaning that such disability was incurred or aggravated in the line of duty in the active military, naval or air service.

Small Business Enterprise (SBE)
"Tennessee small business" means a business that is a continuing, independent, for profit business which performs a commercially useful function with residence in Tennessee and has total gross receipts of no more than ten million dollars ($10,000,000) averaged over a three-year period or employs no more than ninety-nine (99) persons on a full-time basis".

For additional program eligibility information visit,
http://www.tn.gov/businessopp/program_elig.html.

INVITATION TO BID INSTRUCTIONS

As part of this Invitation to Bid, the Respondent should complete the Diversity Utilization Plan, which begins on the following page. To assist in your effort to seek and solicit the participation of diversity businesses on this solicitation, a directory of certified Diversity Business Enterprise firms may be found on the State's website at: http://www.tn.gov/businessopp/regdivcomp.html or by calling Go-DBE toll free at 866-894-5026.

RESPONDENT'S
DIVERSITY UTILAZATION PLAN

Respondent's Company Name:		
Solicitation Event Name:		Event Number:
Respondent's Contact Name:	Phone: ( )	Email:
Does the Respondent qualify as the diversity business enterprise? ___ Yes ___ No If yes, which designation does the Respondent qualify? ___ MBE ___ WBE ___ SDVBE ___ SBE Certifying Agency:		

Estimated level of participation by diversity businesses if awarded a contract pursuant to this ITB:

Diversity Business Information (List all subcontractors, joint-ventures, and suppliers)	**Percent of Contract**	**Estimated Amount**	**MBE/ WBE/ SDVBE/ SBE Designation**	**Currently Certified (Yes or No)**
Business Name: Contact Name: Contact Phone:				
Business Name: Contact Name: Contact Phone:				

If awarded a contract pursuant to this ITB, we confirm our commitment to make reasonable business efforts to meet or exceed the commitment to diversity as represented in our Diversity Utilization Plan. We shall assist the State in monitoring our performance of this commitment by providing, as requested, a quarterly report of participation in the performance of this Contract by small business enterprises and businesses owned by minorities, women, and Tennessee service-disabled veterans. Such reports shall be provided to the State of Tennessee Governor's Office of Diversity Business Enterprise in form and substance as required by said office. We further agree to request in writing and receive prior approval from the Central Procurement Office for any changes to the use of the above listed diversity businesses.

Authorized Signature: _____ Date: _____

Printed Name and Title of Respondent Signatory (above) _____

HOLOGIC®
The Science of Sure

January 19, 2015

To Whom It May Concern:

This letter is to verify that Hologic, Inc. is the sole source of the fully automated, nucleic acid-based system and associated kits and reagents listed below for use in determining the presence of *Chlamydia trachomatis* and/or *Neisseria gonorrhoeae, human papillomavirus (HPV), and Trichomonas vaginalis* in a test sample.

Instrument System

Cat. #303095 Panther® System is covered by U.S. Patent Nos. 6,605,213, 7,135,145, 7,033,820, and 7,638,337.

Assay Kit for Use on the Instrument System

Cat. #303094 Aptima Combo 2® Assay for detection of *Chlamydia trachomatis and Neisseria gonorrhoeae* (250 test kit), and Cat. #302923 Aptima Combo 2 Assay for detection of *Chlamydia trachomatis and Neisseria gonorrhoeae* (100 test kit) are covered by U.S. Patent Nos. 5,514,551, 5,556,771, 5,656,207, 5,658,737, 5,693,468, 5,696,251, 5,723,597, 5,756,709, 5,840,873, 6,090,591, 7,087,742, 7,138,516, and 7,172,863.

Cat. #303585 Aptima® HPV Assay for detection of *human papillomavirus (HPV)* (250 test kit) and Cat. #303570 Aptima HPV Assay for detection of *human papillomavirus (HPV)* (100 test kit) are covered by U.S. Patent Nos. 5,656,207, 5,656,423, 5,658,737, 5,696,251, 5,712,092, 5,756,709, 5,840,873, 5,876,922, 6,090,591 and 6,245,519.

Cat. # 303537 Aptima *Trichomonas vaginalis* Assay for detection of *T. vaginalis* (250 test kit) and Cat. #303536 Aptima *Trichomonas vaginalis* Assay for the detection of *T. vaginalis* (100 test kit) are covered by U.S. Patent Nos. 5,656,207, 5,658,737, 5,696,251, 5,756,709, 5,840,873, 6,090,591, 6,245,519, 6,294,338 and 7,632,934.

The Aptima assays have been validated for use with the Panther System. The firmware in the Panther System is necessary for running the Aptima assays and is unique to Hologic. Hologic is the sole source of this firmware.

Kits and Reagents Associated with the Assay Kits

The following kits and reagents were developed and qualified to be used with the Aptima assays and may include proprietary technology. Hologic is the sole source of these kits and reagents.

*Cat. #301040 Aptima Urine Specimen Collection Kit for Male and Female Urine Specimens
Cat. #301041 Aptima Unisex Swab Specimen Collection Kit for Endocervical and Urethral Swab Specimens
Cat. #301162 Aptima Vaginal Swab Specimen Collection Kit
Cat. #301154C Aptima Specimen Transfer Kit
Cat. #301048 Aptima Auto Detection Reagent Kit
Cat. #301110 Aptima Controls Kit
Cat. #303001 Aptima Assay Fluids Kit

10210 Genetic Center Drive, San Diego, CA 92121

Cat. #303000 Aptima Auto Detect Kit
Cat. #303096 Panther System Run Kit
Cat. #303085 Advanced Cleaning Solution
Cat. #303099 Panther System Start-Up kit

Hologic does not sell through dealers or distributors in the U.S. Sales are made directly to the end user only. Additional patent information can be found by visiting http://hologic.com/patentinformation.

Please do not hesitate to contact me if you should need further assistance.

Sincerely,

Thomas West
Division President, Diagnostics

Gen-Probe Sales & Service, Inc. is a wholly-owned subsidiary of Gen-Probe Incorporated. Gen-Probe Incorporated is a wholly-owned subsidiary of Hologic, Inc.

**LEGAL NOTICE AND DISCLAIMER: The United States Food and Drug Administration (FDA) has not cleared or approved the use of urine collection devices for female urine specimens for use with the Aptima Combo 2 Assay on the Panther System. Accordingly, any such use of urine collection devices shall be at the sole risk of customer and Hologic shall have no liability therefor.*

SPECIFICATIONS for the SIMULTANEOUS NUCLEIC ACID AMPLIFICATION TEST for the DETECTION OF *Chlamydia trachomatis* and *Neisseria gonorrhoeae

JUSTIFICATION:

The TN Department of Health Laboratories in Nashville and Knoxville along with the assistance of the Memphis-Shelby County Laboratory will facilitate testing as recommended for Laboratory-Based Detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* March 2014.

GENERAL SPECIFICATIONS:

- Nucleic Acid Amplification Test (NAAT) for the simultaneous detection of infections of *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) from urogenital infections in male and female patients with and without symptoms in a single assay tube.
- FDA approved method for NAAT.
- FDA approved method from first catch male and female urine, endocervical, urethral and self-collected or clinician collected vaginal swabs. (Not Xpert Cepheid or Roche – due to no urethral swabs; Not BD – no clinician collected vaginal)
- Unidirectional specimen processing procedure to minimize contamination.
- Encourages and will test environmental monitoring to detect environmental amplicon in the laboratory as part of standard molecular method techniques.
- Allows for testing and establishment of performance specifications to detect *Chlamydia trachomatis* and *Neisseria gonorrhoeae* from rectal and oropharyngeal infections, or extragenital sites, to satisfy CMS regulations and CLIA compliance for test modifications from previously tested test specimens.
- Current FDA cleared NAAT that will detect the lymphogranuloma venerum (LGV) serovars (L1, L2, and L3) the biological LGV variant, and the new variant nvCT of *C. trachomatis.*
- No false positive test results determined for *Neisseria gonorrhoeae,* or cross reactivity with nongonococcal Neisseria species. (Not BD may give false positive for N. cinerea N. subflava and N. lactamica)
- Sensitivity and specificity of test for *C. trachomatis* and *N. gonorrhoeae* will not vary with respect to anatomic site from which the specimen was collected and/or specimen type.
- Test system does not require repeat testing of positive NAAT specimens.

- Must allow for a minimum of 30 day transport time with storage of 2^0 C – 30^0 C in transit.
- Automation of test and reporting of both organisms within one workday.
- Must allow direct tube sampling of specimen using a "pierce able" cap.
- Pretreatment of a collected specimen in transport not required. (Not BD)
- Throughput of at least 450 patient specimens with both a CT and GC result for testing in one workday. Not Roche, Xpert Cepheid
- Provides automated onboard sample barcode scanning during testing. Not BD
- Allows for continuous loading of samples and reagents. Not BD
- Ability to reuse remaining test in reagent kit to eliminate waste. Not BD
- Capacity to integrate with the onboard laboratory LIS
- Provide technical support-Technical Assistance:
    - Shall have a toll free number available five (5) days a week, Monday through Friday from 8:00AM – 4:30 PM CST.
    - Vendor shall provide telephone technical support within 24 hours after the initial call.
    - When technical support cannot resolve the problem, vendor shall provide on-site support within 48 hours.
    - Parts will be shipped by overnight carrier to agency location at vendors' expense.
- Vendor shall provide training for additional personnel as needed for each laboratory site with competency achieved in performing the test, proper storage and handling of reagents and specimens, reporting, and interpreting validity of results.

TESTING EQUIPMENT:

Two test instruments per three testing sites in Nashville, Memphis and Knoxville to test for *Chlamydia trachomatis* and *Neisseria gonorrhoeae*

MAINTENANCE SPECIFICATIONS:

- Vendor shall be responsible for all shipping charges produced by the shipment of the equipment to and from the laboratories.
- The State of Tennessee will not be responsible for replacement of equipment in the event of loss due to fire or water damage, or theft.
- Equipment will remain in the state laboratories during the contract period, but remain the property of the vendor.
- The vendor will maintain all equipment in proper working condition or replace improperly functioning equipment at no cost to the state unless the state is guilty of negligence in the operation of said equipment.
- If repairs cannot be made by telephone instructions to laboratory personnel, a service technician will be sent to the laboratory within 48 hours of notification by state to the vendor.
- Replacement parts and equipment will be shipped to the state by overnight delivery to be received next day at no additional costs.
- Upgrades made by vendor will be made available at no additional cost of the state.

***Recommendations for the Laboratory-Based Detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* — 2014 MMWR March 14, 2014**

http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6302a1.htm

HOLOGIC®
The Science of Sure

February 17, 2015

Tennessee Department of Health
Attn: Jim Gibson
630 Hart Lane
Nashville, TN 37216

Dear Jim Gibson,

Thank you for your interest in Hologic's line of diagnostic and cytology products. We are pleased to quote the following pricing and annual commitment.

Term: 60 Months

Product	Annual Test Volume	Test Price
APTIMA Combo2 CT/GC	130,000	$ 7.25
APTIMA HIV-1 RNA	1,200	$ 40.00
Collection Devices	130,000	see chart below

The commited volume may be comprised of any of the kit types or sizes below.

Product Number	Product Description	Kit Size	Price/Kit
303094	APTIMA COMBO 2 Assay: 250 PANTHER	250	$ 1,812.50
302923	APTIMA COMBO 2 Assay: 100 PANTHER	100	$ 725.00
302178	Kit, Aptima, HIV-1 RNA QL, Sales BOM	100	$ 4,000.00

The following Collection Devices will be available to you:

301040	Kit,APTIMA COMBO 2 Urine Spec Coll	50	$ 62.50
301041	Kit,APTIMA COMBO 2 Swab Spec Coll	50	$ 62.50
301162	Collect Kit,Vaginal Swab (IVD)	50	$ 62.50
301154C	Kit, APTIMA LPT-IVD Sales BOM	100	$ 120.00

Additional products that will be available to you include.

Product Number	Product Description	Price
303096	Run Kit, PANTHER	No Charge
CL0040	Caps, TCR/SEL.(CL0038) DIAG.	No Charge
CL0041	Caps, AMP/P.R.S.(CL0045)DIAG.	No Charge
303085	Lbld, Advanced Cleaning Solution, 255 mL	No Charge
501604	Spare Caps, PP, 60mL, TCR APTIMA 2x50	No Charge
501616	Spare Caps,30mL tube (501213)Diagnostics	No Charge
301110	APTIMA CT/GC Cntrls Kit (1 tray) IVD	No Charge
105668	APTIMA PENETRABLE CAPS	No Charge
TU0022	Ten Tube Unit, TCS	No Charge
104578	Ten Tip Cassette, TCS	No Charge
105049	Tip, P1000 Style, 1000 ul	No Charge
302782	APTIMA HIV QUAL Calibrator Kit	$ 400.00
302162	Aptima QL Auto Detect Reagents, Sales BOM	$ 90.00
302160	Aptima HIV-1 Prof Panel, Sales BOM	$ 2,500.00

The following instrumentation will be provided:

Product Number	Instrumentation	Units	Unit Price
303095	PANTHER	6	$0
302722	DTS 400	1	$0
104586	Waterbath, Man Combo, Precision	3	$0
Total Instrumentation Price		**Total**	**$0**

This document is provided for quoting purposes only. To take advantage of this pricing, Customer and Hologic must enter into a signed agreement. Payment terms: 30 days. Offer valid through March 27, 2015.

To begin the site assessment process, please fax to: 866-523-6828

If you should need further assistance, do not hesitate to call me personally at 615-686-8803

Sincerely,

Paula Stokes
Hologic Account Executive

Please be advised, TECAN tip (catalog # 10612513) are the only tips that Hologic has validated for use on the Panther® System ("System"). Hologic does not support the use of non-TECAN tips on the System as stated in the System Operator's Manual and pursuant to the terms of the warranty for the System. The TECAN tip (catalog #10612513) can be directly ordered from TECAN U.S. at 800-338-3226.

Upon installation of the System Upgrade, Customer agrees to return the two Tigris Systems (Serial #1250 and #1251) to Hologic. Once the Tigris equipment is returned to Hologic, the Tigris Reagent portion of the contract will no longer be active. Hologic will pay freight for both the shipment of the new Panther Systems to Customer and return of the Tigris Systems to Hologic.

If you have any questions please contact your Hologic Account Executive, Paula Stokes at (615) 686-8803.

Sincerely,

Joanne Dada
Senior Manager, Sales and Contracts Administrator

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