

CONTRACT #1
RFS # NA
Edison # Pending

Department of Health
Laboratory Services

VENDOR:
PerkinElmer Health Sciences



STATE OF TENNESSEE
DEPARTMENT OF HEALTH

JOHN J. DREYZEHNER, MD, MPH
COMMISSIONER

BILL HASLAM
GOVERNOR

September 19, 2014

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

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

Dear Director Geise and CPO Perry:

The Department of Health is requesting sole source approval to establish a multi-year contract for the purchase of reagents to perform testing on newborns as per rules and regulations of DOH under Chapter 1200-15-1. The reagents test for Aminoacidopathies, Urea Cycle Disorders, Organic Acidopathies and Beta Fatty Acid Oxidation Disorders by Tandem Mass Spectrometry. All tests are run using a 1/8" spot of dried blood. Other methods would require blood be collected by conventional means into a vacutainer tube which is not an acceptable method as newborns do not have an abundance of blood in their circulatory system. Tennessee Code Annotated 68-5-401 mandates these disorders be screened on all infants born in the State of Tennessee.

It is essential these tests be conducted to identify potential health concerns which can be treated immediately, in some cases by a change in diet, enabling normal growth and development of the infant. The kits purchased must be compatible with the Perkin Elmer instrument which will be provided through this contract along with the consumables at no additional charge to the State Laboratory. Furthermore, Perkin Elmer provides maintenance and software updates. This methodology is FDA approved which is a requirement of Laboratory licensing agency CLIA.

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

Sincerely,

A handwritten signature in blue ink, appearing to read "John J. Dreyzehner", is written over a blue circular stamp.

John J. Dreyzehner, MD, MPH, FACOEM
Commissioner

Supplemental Documentation Required for
Fiscal Review Committee

*Contact Name:	Chris Dorley Jim Gibson	*Contact Phone:	615-262-6352 615-262-6303		
*Presenter's name(s):	Jim Gibson				
Edison Contract Number: <i>(if applicable)</i>		RFS Number: <i>(if applicable)</i>			
*Original or Proposed Contract Begin Date:	12/12/14	*Current or Proposed End Date:	12/11/19		
Current Request Amendment Number: <i>(if applicable)</i>					
Proposed Amendment Effective Date: <i>(if applicable)</i>					
*Department Submitting:		Department of Health			
*Division:		Laboratory Services			
*Date Submitted:					
*Submitted Within Sixty (60) days:		Yes			
<i>If not, explain:</i>					
*Contract Vendor Name:		Perkin Elmer			
*Current or Proposed Maximum Liability:		\$4,757,480.00			
*Estimated Total Spend for Commodities:		\$4,757,480.00			
*Current or Proposed Contract Allocation by Fiscal Year: <i>(as Shown on Most Current Fully Executed Contract Summary Sheet)</i>					
FY: 2014	FY: 2015	FY: 2016	FY:2017	FY2018	FY2019
\$475,748.00	\$951,496. 00	\$951,496.0 0	\$951,496.00	\$951,496.0 0	\$475,748.00
*Current Total Expenditures by Fiscal Year of Contract: <i>(attach backup documentation from Edison)</i>					
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					

Supplemental Documentation Required for
Fiscal Review Committee

was acquired to pay the overage:			
*Contract Funding Source/Amount:			
State:	100%	Federal:	
<i>Interdepartmental:</i>		<i>Other:</i>	
If "other" please define:			
If "interdepartmental" please define:			
Dates of All Previous Amendments or Revisions: <i>(if applicable)</i>		Brief Description of Actions in Previous Amendments or Revisions: <i>(if applicable)</i>	
Method of Original Award: <i>(if applicable)</i>			
*What were the projected costs of the service for the entire term of the contract prior to contract award? How was this cost determined?		The projected cost is based on a quote from the vendor and the usage shown in the past year by laboratory personnel.	
*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.		Perkin Elmer is the sole manufacturer and distributor of FDA approved test kits using the 1/8' dried blood spot. Newborns do not have sufficient blood supply to obtain blood samples through a vacutainer tube.	

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 #	- HL00000288
1. Contracting Agency	Tennessee Department of Health/Laboratory Services
2. Type of Contract or Procurement Method	<input type="checkbox"/> No Cost <input type="checkbox"/> Revenue <input checked="" type="checkbox"/> Sole Source <input type="checkbox"/> Proprietary <input type="checkbox"/> Competitive Negotiation <input type="checkbox"/> Other _____
3. Requestor Contact Information	Christine Dorley Tennessee DOH/Lab Services RS Gass Building 5 th floor 630 Hart Lane Nashville, TN 34243
4. Brief Goods or Services Caption	MS/MS Neobase Combined Amino Acid and Acylcarnitine and Specimen Gate Lab testing
5. Description of the Goods or Services to be Acquired	Reagents, instrumentation, and software (to manage QC data for multiple assays) and maintenance to comply with rules and regulations of DOH under Chapter 1200-15-1.
6. Proposed Contractor	PerkinElmer, Inc.
7. Name & Address of the Contractor's principal owner(s) - NOT required for a TN state education institution	PerkinElmer, Inc. 710 Bridgeport Avenue Shelton, CT 06484-4794 USA Phone 800 762 4200 x1 x2 Fax 203 762 4901 www.perkinelmer.com

Request Tracking #	- HL0000288
8. Proposed Contract Period – with ALL options to extend exercised <i>The proposed contract start date shall follow the approval date of this request.</i>	60 months
9. Office for Information Resources Pre-Approval Endorsement Request <i>– information technology (N/A to THDA)</i>	<input checked="" type="checkbox"/> Not Applicable <input type="checkbox"/> Attached
10. eHealth Pre-Approval Endorsement Request <i>– health-related professional, pharmaceutical, laboratory, or imaging</i>	<input checked="" type="checkbox"/> Not Applicable <input type="checkbox"/> Attached
11. Human Resources Pre-Approval Endorsement Request <i>– state employee training</i>	<input checked="" type="checkbox"/> Not Applicable <input type="checkbox"/> Attached
12. 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.	<input checked="" type="checkbox"/> NO <input type="checkbox"/> YES,
13. Maximum Contract Cost – with ALL options to extend exercised	\$4,757,480.00
14. Was there an initial government estimate? If so, what amount?	<input type="checkbox"/> NO <input checked="" type="checkbox"/> YES, \$4,757,480.00
15. Cost Determination Used- How did agency arrive at the estimate of expected costs?	Quotation obtained from the vendor.
16. Explanation of Fair and Reasonable Price- Explain how agency determined that price is fair and reasonable	Reagent contract to include reagents and instrumentation, software and services to test for disorders by Tandem Mass Spectrometry mandated by DOH rules Chapter 122-15-1. This is a sole source vendor. Perkin Elmer has the only FDA approved kit and this kit can only be obtained through this vendor (See sole source documentation).
17. Documentation of Discussions with Contractor- How did agency document discussions with Contractor? Attach documentation to this request as applicable.	Vendor visited Laboratory and we had email and phone discussions concerning contract renewal.
18. Explanation of Need for or requirement placed on the State to acquire the goods or services	Tests are mandated by rules and regulations of the DOH under Chapter 122-15-1.
19. Proposed contract impact on current State operations	Contract will allow laboratory to meet rules and regulations of the State of Tennessee.

Request Tracking #	- HL00000288
20. Justification – Specifically explain why the goods or services should be acquired through the procurement method or contract type selected.	Perkin Elmer is the only vendor who can provide FDA approved test kits which only requires 1/8" of dried blood be used for testing. Other methods require blood be collected by conventional means into a vacutainer tube which is not an acceptable method as newborns do not have an abundance of blood in their circulatory system. This reagent contract will provide the means necessary to meet the requirements for testing of newborns throughout the state. Test kits must be FDA approved to meet requirements of our licensing agency CLIA. Testing allows the Laboratory to follow the rules and regulations of DOH under Chapter 1200-15-1 for newborns.
For No Cost and Revenue Contracts Only	
21. What costs will the State incur as a result of this contract? If any, please explain.	
22. What is the total estimated revenue that the State would receive as a result of this contract?	
23. Could the State also contract with other parties interested in entering substantially the same agreement? Please explain.	<input type="checkbox"/> NO <input type="checkbox"/> YES
24. Summary of State responsibilities under proposed contract	
For Sole Source and Proprietary Procurements Only	
25. Explanation of Need for or requirement placed on the State to acquire the goods or services	Tests are mandated by rules and regulations of the DOH under Chapter 1200-15-1.
26. Evidence of Contractor's experience & length of experience providing the goods or services to be procured.	Contractor has provided these goods to State of Tennessee through reagent and rental since 2007. Contractor has been in business since 1937.
27. 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.	<input type="checkbox"/> NO <input checked="" type="checkbox"/> YES, Method: Sole source reagent and rental contract Name/Address: PerkinElmer, Inc. 710 Bridgeport Avenue Shelton, CT 06484-4794 USA Phone 800 762 4200 x1 x2 Fax 203 762 4901 www.perkinelmer.com

Request Tracking #	- HL00000288
28. Contractor selection process and efforts to identify reasonable, competitive, procurement alternatives	Test kits must be FDA approved for MS/MS testing. Testing is required by DOH rules and regulations.
Signature Required for all Special Contract Requests	
<p>Agency Head Signature and Date – <i>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</i></p> <div style="text-align: center; margin-top: 20px;">   </div> <p>Signature: _____ Date: _____</p>	



Terms and Conditions

Event Number: **34301-000000XXXX**

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 - Examination/Audit: The state may, at reasonable times, examine/audit the books and/or records of any vendor/ contractor where such books and/or records relate to the performance of any contract or subcontract with the state. Such books and records shall be kept in conformity with generally accepted accounting principles and maintained by the vendor/contractor or subcontractor for a period of three (3) years from the date of final payment under the prime contract or subcontract. Said examination/audit may be performed at any reasonable time by the Central Procurement Office, the Comptroller of the Treasury, or their duly appointed representative(s).

36. 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.

Special Terms and Conditions

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

F.O.B. Point:

Agency Name: Department of HealthAddress:630 Hart Lane
Nashville, TN 37216-2006

2. 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 offense 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.

3. Term of Contract - Multi-Year

Total Number of Years if all Options are Exercised: 5

Initial Contract Term With 0Renewal

Start Date: December 12, 2014

Initial End Date: December 11, 2019

Final End Date: December 11, 2019

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.

4. Volume, Multi-Year

The total purchases of any individual item on the contract are not known. The Central Procurement Office has attempted to give an accurate estimate of probable purchases of each 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.

Purchases Current Contract Period \$ 664,452.00

Dates: From December 12, 2013 To December 11, 2014

Estimated Funding New 4,757,480.00

1st 12 MONTHS \$ 951496.00

2nd 12 MONTHS \$ 951496.00

3rd 12 MONTHS \$ 951496.00

4th 12 MONTHS \$ 951496.00

5th 12 MONTHS \$ 951496.00

The vendor/contractor will only be paid for products or services rendered hereunder pursuant to purchase order releases issued to vendor/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 vendor/contractor and does not guarantee payment of any such funds to the vendor/contractor per year under this contract unless the state requests product or service and vendor/contractor provides said product or service. The state is under no obligation to request product or service from vendor/contractor in any specific dollar amounts per year under this contract and the state may not request any product or service at all from vendor/contractor during the contract period.

5. 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.

6. 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.

7. Delivery Time (On-Time)

The contractor shall be required to maintain or to have available for their own use personnel, equipment, and products sufficient to perform "on-time" as specified in this Invitation to Bid.

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.

8. 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.

9. 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.

10. 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.

11. 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.

12. 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 respondent 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.

13. 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.

14. 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.

15. 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.

16. 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

17. 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:

18. 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.

19. 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.

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. 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

The following shall be completed by the bidder. The following is a list of acceptable responses:

1. The bidder can copy the document to their computer, fill out the form and re-attach it to the bid.
2. The bidder can attach or send its company's diversity business policies with the bid.
3. The bidder can attach or send responses to the Good Faith Efforts, Diversity Business Participation, and the Diversity Utilization Plan with the bid.

EFFORTS TO ACHIEVE DIVERSITY BUSINESS ENTERPRISE PARTICIPATION

The Governor, in an effort to expand economic opportunities for small businesses and businesses owned by minorities and women in Tennessee, issued Executive Order Number 14 on December 8, 2003, which created the Governor's Office of Diversity Business Enterprise (Go-DBE). In 2004, to further facilitate the State's efforts to promote greater participation by minority owned, woman owned and small businesses in its procurement and contracting opportunities, the General Assembly passed legislation amending Tennessee Code Annotated 12-3-801 through 808 establishing the "Tennessee Minority Owned, Woman Owned and Small Business Procurement and Contracting Act." July 1, 2010 Public Chapter No. 1140 became effective by amending Title 12, Chapter 3, and Part 8 relative to include service-disabled veteran owned businesses. To coordinate this effort, Go-DBE and the Department of General Services' Central Procurement Office have implemented the following procedure:

The vendor or prime contractor should contact appropriate sources within its geographic area to identify qualified minority owned, woman owned, service-disabled veteran owned and small businesses for this purpose. If needed, the Governor's Office of Diversity Business Enterprise can provide a list of minority owned, woman owned, service-disabled veteran owned and small businesses who provide an array of services or a vendor may advertise in a newspaper with one or more wide-circulation publications to enhance the solicitation of proposals from minority owned, woman owned, service-disabled veteran owned and small businesses.

To assist you in your effort to seek and solicit the participation of minority owned, women owned, service-disabled veteran owned or small 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 the Governor's Office of Diversity Business Enterprise toll free at 866-894-5026. If you are currently utilizing a minority owned, women owned, service-disabled veteran owned or small business that is not listed in the State's directory, please provide its company name, address and telephone number in the space provided. We will assist them in registering with the Governor's Office of Diversity Business Enterprise.

Please complete the attached form and include all pertinent documentation regarding your company's efforts to achieve diversity business participation. This information must be submitted with the bid document and monthly thereafter until a reasonable level of diversity business participation is achieved.

GOOD FAITH EFFORTS

GOOD FAITH EFFORTS UNDERTAKEN BUT NOT LIMITED TO THE FOLLOWING ACTIONS (PROVIDE SPECIFIC DOCUMENTATION FOR EACH EFFORT CHECKED)

- 1) ___ Contacted diversity businesses that reasonably could have been expected to submit a quote and that were known to the contractor or available on the Go-DBE Directory. (Provide a list of minority, women, service-disabled veteran owned and small businesses who were contacted. Indicate whether the diversity business responded or followed up to your solicitation request.)
- 2) ___ Make the specifications and requirements of this procurement available for review by prospective diversity businesses at least ten (10) days before the bid or proposals are due.
- 3) ___ If possible, breaking down or combining elements of work into economically feasible units to facilitate diversity business participation.
- 4) ___ Work with minority, women, service-disabled veteran owned, and small business trades, community organizations, or minority, women, service-disabled veteran owned or small business organizations identified by Go-DBE to obtain diversity businesses participation, whenever possible.
- 5) ___ If possible, provide assistance in getting required bonding or insurance or providing alternatives to bonding or insurance for diversity business subcontractors.
- 6) ___ Negotiate in good faith, with interested diversity businesses, and not reject them as unqualified without sound reasons based on lack of qualification, and document in writing the reasons for exclusion.
- 7) ___ If possible, provide assistance to an otherwise qualified diversity business in need of equipment, loan capital, lines of credit, or joint pay agreements to secure loans, supplies, or letters of credit, including waiving credit that is ordinarily required. Assist diversity businesses in obtaining the same unit pricing with the bidder's suppliers, in order to help diversity businesses establish credit.
- 8) ___ If possible, negotiate joint venture and partnership arrangements with diversity businesses in order to increase opportunities for diversity business participation on this procurement.
- 9) ___ If possible, provide quick pay agreements, and policies to enable diversity businesses and suppliers to meet cash-flow demands.
- 10) ___ Other effort. (Please provide details of efforts made to obtain diversity participation on the procurement).

DIVERSITY BUSINESS PARTICIPATION:

In order to achieve Diversity Business participation, certified **MINORITY-OWNED, WOMEN-OWNED, SERVICE-DISABLED VETERAN OWNED, AND SMALL-OWNED BUSINESSES** are expected to participate in the following manner.

MBE/WBE/ SDVBE/SBE Firm	Description of Work (MBE/WBE/ SDVBE, SBE)	Projected Contract Amount and Award Date	Contract Schedule Start Date	Contract Payment Schedule	Project Completion Date
Name: Address: City: State/Zip Code: Phone: E-mail:					
Name: Address: City: State/Zip Code: Phone: E-mail:					

DIVERSITY UTILIZATION PLAN

CONSULTANT/CONTRACTOR DETAILED MBE/WBE/SDVBE/SBE PLAN

Business/Company/Vendor Name:		
Event/Contract Number:		Award Date:
Address:	City:	State: Zip Code:
Event/Contract Description: (Brief Description of Project)		
Business/Company/Vendor Contact Name:		Phone: E-Mail:

PROJECTED MBE/WBE/SDVBE/SBE BID SUMMARY

	%	Amount		Amount
1. Total Dollar Value of the Contract	100%	\$		
2. MBE Projected Goal Applied to the Contract	____%	\$	6. Total MBE Dollar Amount Met	\$
3. WBE Projected Goal Applied to the Contract	____%	\$	7. Total WBE Dollar Amount Met	\$
4. SDVBE Projected Goal Applied to the Contract	____%	\$	8. Total SDVBE Dollar Amount Met	\$
5. MBE/WBE/SDVBE Combined Projected Goals	____%	\$	9. Combined Total MBE/WBE/SDVBE Dollar Amount Met	\$

Go-DBE PROGRAM USE ONLY

		Date Approved	Date Disapproved	Initials
MBE (%)	Minorities (%)			
WBE (%)	Female (%)			
SDVBE (%)	Service-disabled veteran (%)			

)



**QUOTATION FOR MSMS NEOBASE COMBINED AMINO ACID AND
 ACYLCARNITINE AND SPECIMEN GATE LAB**

September 9, 2014

Tennessee Department of Health
 Laboratory Services
 Genetic Screening
 630 Hart Lane
 Nashville, TN 37216

Attn: M. Christine Doyle, Director Newborn Screening

Pricing based on 115,200 tests per year
 Term: 5 years

Quarterly fee includes reagent kits, instrumentation, service contract,
 software and support

Quote Ref #	Quote Expires	FOB	Area Manager	Terms
080814-JB1	September 30, 2014	Boston, MA Shipping Charges Apply	Jeanne Brunger Cell phone: 205-746-4113	Net 30
Quarterly Fee Product code: NPNEO-MS			237,874.00	
Total per year			\$951,495.00	

Quarterly fee includes the reagent kits and quantities shipped during the contract year is listed below.

REAGENTS		
Product No.	Description	Yearly Quantity
	<i>AA & AC kit not requiring derivitization of the specimen</i>	
3040-001U	NeoBase AA & AC kit for MSMS (960 tests).	120
3042-0020	NeoBase Succinylacetone Solution (960 tests)	120

Notes:

Shipping charges are included, in quarterly fee.

One solutions pack is shipped with each kit. Additional kits can be purchased at the price noted below.

If additional kits are needed during contract year, they may be purchased at the price below.

ADDITIONAL REAGENTS		
Part #	Description	Unit Price
3040-001U	NeoBase Combined Amino Acid and acylcarnitine for non-derivitized specimens. Includes controls and internal standards, plates, plate covers. Includes 1 NeoBase Solutions Pack at no charge	4,194.00
3042-0020	NeoBase Succinylacetone Solution (960 tests)	623.00
3041-0020	NeoBase Solutions Pack for use with 3040-0010 (960 tests)	674.00

Notes:

Shipping charges are included in price of the kit.

The use of following instrumentation and equipment with service contract is included in the quarterly fee.

INSTRUMENTATION		
Qty	Part #	Description
2	1445-006	PerkinElmer TQD MSMS Screening System to include: AutoSampler: 12 plate capacity Roughing Pump HPLC Pump Computer and NeoLynx Software Laser Printer Peak Nitrogen Generator: model N11DR (dual compressor) UPS: for Rough Pump, Instrument, Computer, AutoSampler
3	1296-0050	TriNEST incubator shaker

SERVICE		
QTY	Part #	Description
2	GASGENERATORP EAK	Peak Gas Generator (N11DR)
3	GDS1296-0050	TriNEST
2	UPS Device 5kVA 220V	Un-interruptible Power Supply
2	GDS1445-006	TQD MSMS Screening System: see instruments

The following software is included in the quarterly fee.

Process and Data Management Software			
Qty		Description	Price
1	5003-0320	Configuration Specimen Gate Laboratory	Included in price of reagent kits
1	5002-0180	Annual Subscription Specimen Gate Laboratory	Included in price of reagent kits
1	5003-0530	Annual support contract	Included in price of reagent kits

Products:

Every PerkinElmer software product is distributed subject to license terms which govern the customer's installation, use and disposition of the software. The terms of such license are included with the software product in clickwrap or shrinkwrap form and can also be obtained from PerkinElmer upon request.

Refer to the attached "Product Description" for the product features of the core software modules included with this proposal. Additional features included as part of this proposal, or existing features that require clarification, are described in the Implementation Services section below. Please note that features that are not available as part of the core software modules or that are not listed below are not included as part of this proposal. Requests for such features shall go through PerkinElmer's product development process for potential inclusion in a future core product release.

The software may require the Customer to initiate process changes and is not intended to replace all of the features of the current software system.

Implementation Services:

Should this proposal be accepted, the Customer will be asked to comply with the attached "Software Deployment Terms & Conditions" and "Software Change Request Process". The Implementation Services will be conducted primarily at PerkinElmer facilities and will be scheduled upon receipt of a purchase order, contract, or mutually agreed upon Statement of Work.

The following instruments (and associated analytes) will be interfaced with the software via the instrument control PC:

Instrument	Instrument Software	# of Instruments	Analytes
MultiPuncher and/or Panthera-9	N/A	3	N/A
DBS Puncher	N/A		N/A
Waters TQD MSMS	MassLynx/NeoLynx	2	MSMS Neobase
GSP	GSP workstation	2	TSH, 17-OHP, IRT
Victor EnLite System	EnLite workstation	TBD	TREC, 2 nd marker

The following disorders will be configured in Specimen Gate®:

- Congenital Hypothyroidism
- Phenylketonuria
- Congenital Adrenal Hyperplasia
- Cystic Fibrosis
- Fatty Acid Disorders, Amino Acid Disorders, and Organic Acid Disorders screened by TN as of Dec 31 2014.

The following implementation activities will be provided:

- Compilation of software specifications with the Customer
- Configuration of the features described in the “Product Description”, this proposal, and the configuration requirements
- Bi-directional interface with instruments and instrument software systems listed in the table above to the Specimen Gate System:
 - Configuration of the puncher software to create an electronic worklist to be used by instrument. The functionality of this will be dependent on the instrument software.
 - NOTE: The puncher software to create an electronic worklist is only compatible with the following punching instruments.
 - PerkinElmer Panthera P-9
 - PerkinElmer Multipuncher
 - PerkinElmer DBS puncher
 - Configuration of Specimen Gate® import routine to import results file that contain qualitative or quantitative result values.
 - This result file MUST be in a specific format to be imported into the Specimen Gate® database. Specimen Gate will provide the instrument vendor with a sample result file format.
 - This file will be put on a network location accessible from the Specimen Gate database server.
- Cystic Fibrosis (CF) testing will be configured to use IRT as the screening test with CF DNA Mutation Analysis as the confirmation test.

- For all disorders listed above (excluding CF), testing is performed using the same analyte for both initial and confirmatory testing.
- Creation of customer specific disorder logic for TSH, IRT, 17OHP, TREC, SCID 2nd marker, and MSMS analytes
 - Disorder Logic can include demographic variable (i.e. age, weight, transfusion status) cutoff values
 - Up to 15 analytes can be configured using demographic variable cutoff values
 - Each demographic variable cut-off can have no more than four tiers (i.e. Age of Collection NULL, <24 hr, >=24 and <=48, >48)
 - Up to 5 analytes can be configured with logic that treats a 2nd specimen differently when a 1st specimen is at risk
 - Disorder flagging criteria must be identical for each analyte for the 1st and 2nd specimens unless unique accession numbers can be applied to identify a second specimen
- Configuration of HPLC, GALT, BIO, and TGAL analytes in Result Viewer
 - Analyte Flagging
 - Single Analyte flagging will be configured
 - Multi-analyte flagging and demographic-based flagging is not included for these analytes with this proposal.
 - QC viewing and flagging is not included in this proposal for these analytes.
 - Importing instrument flags, drawing concentration curves, and plotting Levey-Jennings plots are not available
- All specimen results will be imported into the Cutoff Analyzer module
- The following will not be available for home-brew assays:
 - Sample Spectra, TIC or XIC
 - Standard curve calculations
- Assisting with the Customer's system acceptance testing

The following training and materials will be provided:

- End user manuals for the core product along with the completed software specification documents comprise the system documentation
- Installation instructions
- One demonstration-style class in a Customer provided room during the creation of the software specifications to familiarize customer with software as they are making configuration decisions
- One-time hands-on training class in a Customer provided room before the go-live date
- Continuous on the job training

Should this proposal be accepted, the Customer will be asked to:

- Provide signoff within 15 business days after the go-live date. This signoff verifies the delivery of the agreed upon software configurations and acknowledges the project is complete. Note that if signoff is not received within 15 business days the customer is requested to submit a formal issue list to PerkinElmer, which PerkinElmer will then

respond to. If neither sign-off nor a formal issue list is achieved within 15 business days of the go-live date final acceptance of the system is implied and PerkinElmer may invoice for the full amount of the contract and begin support.

Support Services:

Refer to the attached "Software Support Terms and Conditions" for details.

Hardware and Third Party Software:

For all hardware and third party software the Customer assumes the responsibility for:

- Hardware support and maintenance as defined in the Deployment Terms and Conditions.
- All fees related to replacing or upgrading hardware.
- All fees related to upgrading third party software and/or adding software licenses.

For all hardware PerkinElmer assumes the responsibility for:

- Installation of PerkinElmer products.

Payments:

The purchase order for the quarterly fee should be for 4 NPNeo-MS per contract year, and the kits will be shipped at \$0.0

Price Increases:

Prices for the quarterly fixed fee and additional kits will be firm for the first contract term. There may be an increase on the renewals. A price increase will be based on the cumulative CPI (Consumer Price Index) for the previous 12 months and PerkinElmer published List Price increases of the products included in this contract. The contract price increase will have a limit of not more than 5% per renewal year.



PerkinElmer Health Sciences.
Diagnostics Customer Care
710 Bridgeport Ave.
Shelton, CT 06484

Phone
800-762-4000 Option 1, 2
Fax
203-944-4901
Email
GDS.Sales@PerkinElmer.com
www.perkinelmer.com

September 5, 2014

Tennessee Department of Health
Laboratory Services
Genetic Screening
630 Hart Lane
Nashville TN 37247-0801

Attention Chris Dorley, Director Genetic Screening

Re: Sole Source Letter Regarding PerkinElmer Products

Dear Ms. Dorley:

In accordance with your request, PerkinElmer Health Sciences, Inc. submits the following for your information. PerkinElmer Health Sciences, Inc. currently offers two FDA cleared kits for testing Amino Acid and Acylcarnitines.

3040-001U	NeoBase Non-derivatized MSMS kit
3041-0020	NeoBase Non-derivatized Assay Solution
3042-0020	NeoBase Succinylacetone Assay Solution

Both the NeoGram and NeoBase kits and solutions shown above are manufactured by PerkinElmer Health Sciences, Inc. PerkinElmer is also the only source for the NeoBase kits and solutions

5003-0320 Configuration Specimen Gate Laboratory

PerkinElmer is also the sole supplier for the maintenance and support of the Specimen Gate Newborn Screening Laboratory information products. Support of these modules requires access and possible change to source code for many of the Specimen Gate modules, which is the intellectual property of PerkinElmer Inc. Working with the source code of the products requires extensive training and experience, which is only available from PerkinElmer software support.

If you should have any questions, please feel free to contact the undersigned at 800-762-4000

Very truly yours,


Craig Cornut
Diagnostics Customer Care

SPECIFICATIONS

Vendor to provide instrumentation, service and support to run the FDA cleared AA AC reagent kits. Instruments, Equipment and Software

- A. Two (2) MS/MS systems as specified in the package inserts of the FDA cleared AA AC reagent kits to include the following components:
- Micro MSMS Detector with roughing pump
 - Binary HPLC pump with vacuum degasser
 - Auto-Sampler with minimum of 6 plate capacity
 - Gas generation system
 - Computer and monitor
 - Printer
 - System operation Software: Mass Lynx and NeoLynx
 - Uninterruptable Power Supply: to back up MS/MS device, computer, HPLC pump and autosampler.
- B. sample preparation equipment:
- Incubator shakers to process in 6 plate batches. Each incubation temperature will require incubator(s) to process 6 plates.
 - 1 Plate sealer
- C. Specimen Gate MS/MS Data Analysis Software
- Agency to provide hardware including operating systems i.e. server, and workstations,
- D. Installation:
- Vendor to provide all equipment, labor and manpower required to install instruments to fully operational stage
- E. Training:
- Vendor to provide training for a maximum of 5 laboratory personnel for 2 days. No travel, hotel, or per diem charges will be paid by the state.
- F. Technical Support:
- Vendor will provide toll free number for technical assistance between 7:00 AM and 4:00 PM Central Time. Vendor will provide a telephone response within 24 hours of call. On site response time will be within 48 hours of the agency's request for service if telephone assistance does not correct the problem.
 - State of Tennessee will not pay for overtime pay after the states normal working hours.

G. Maintenance:

- Vendor will be responsible for all repairs and preventive maintenance procedures on the instruments and equipment provided to run the AA AC Reagent kits per the original vendor's maintenance manuals.
- The vendor will be responsible for parts and supplies other than solvents needed to repair and maintain the instruments. The agency will be responsible for User Maintenance procedures per the vendor's instructions in the maintenance manuals. The agency will be responsible for the supplies used to perform user maintenance.
- The state will not be responsible for replacing the instruments in case of loss due to fire or theft.

Reagents

A. Combined Amino Acid and Acylcarnitine kit – non derivitized

- Shall contain 960 tests (10 plates)
- 13 Amino Acid internal standards and 13 Acylcarnitine internal standards
- Shall include all materials necessary to run combined AA/AC method including controls
- Size: 8.5"x5"x6"
- Weight: 2.5lbs
- Kit must be FDA cleared

Quarterly pricing shall include the cost of the following:

2 Each MS/MS Instruments

30 Kits of the Neobase AA & AC Kit, vendor number 3040-001U

30 Each of the Neobase Succinylacetone Solution, vendor number 3042-0020