CONTRACT #7
RFS # Pending
Edison # Pending

Department of Health
Laboratory Services

VENDOR:
PerkinElmer Health Sciences, Inc.

STATE OF TENNESSEE
DEPARTMENT OF HEALTH

JOHN J. DREYZEHNER, MD, MPH
COMMISSIONER

BILL HASLAM
GOVERNOR

April 20, 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 for the testing of Severe Combined Immunodeficiency Disorder (SCID). SCID is a disorder in which infants are born without an immune system so are unable to fight off diseases. Babies with SCID appear normal initially but subsequently become very ill and most often succumb to simple infections like the common cold. Early detection and diagnosis is the key to curing SCID. Infants diagnosed with SCID must have a bone marrow transplant before three months of age to make a full recovery. Tennessee Code Annotated 68-5-401 mandates inborn errors of metabolism and other genetic disorders be screened on all infants born in the State of Tennessee.

The vendor will also provide the instrumentation, software, updates and maintenance at no additional charge. This is the only FDA approved method available commercially. In addition this method meets the requirements of the lab licensing agency CLIA. The total cost of this contract is $2,960,000.00.

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:	July 1, 2015	*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:	Perkin Elmer		
*Current or Proposed Maximum Liability:	1,776,000.00		
*Estimated Total Spend for Commodities:	1,776,000.00		

*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
$592,000	$592,000	$592,000			

*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?	Projected cost was estimated on a bid submitted by the sole source vendor.
*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.	Reagents and instrumentation is the only FDA approved to test for severe combined immunodeficienty disorders on all newborns in the state as mandated by TN law, Chapter 1200-15-1

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 #	–
1. Contracting Agency	Tennessee Department of Health/Laboratory Services
2. Type of Contract or Procurement Method	☐ No Cost ☐ Revenue ☒ Sole Source ☐ Proprietary ☐ Competitive Negotiation ☐ Other _____
3. Requestor Contact Information	Christine Dorley Tennessee DOH/Lab Services RS Gass Building 5th floor 630 Hart Lane Nashville, TN 34243
4. Brief Goods or Services Caption	En-Lite TREC reagent rental contract
5. Description of the Goods or Services to be Acquired	Perkin Elmer is the sole manufacturer, sole distributor and sole supplier of the En-LITE TREC asay. This assay is used to test for Severe Combined Immunodeficienty Disorder and is the only FDA approved test kit on the market. SCID testing is mandated by rules and regulations of the DoH under Chapter 1200-15-1.

Request Tracking #	–
6. Proposed Contractor	**Perkin Elmer, 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**
8. Proposed Contract Period *– with ALL options to extend exercised* ***The proposed contract start date shall follow the approval date of this request.***	**60 months**
9. Office for Information Resources Pre-Approval Endorsement Request *– information technology (N/A to THDA)*	☒ **Not Applicable** ☐ **Attached**
10. eHealth Pre-Approval Endorsement Request *– health-related professional, pharmaceutical, laboratory, or imaging*	☒ **Not Applicable** ☐ **Attached**
11. Human Resources Pre-Approval Endorsement Request *– state employee training*	☒ **Not Applicable** ☐ **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.	☒ **NO** ☐ **YES,**
13. Maximum Contract Cost *– with ALL options to extend exercised*	**$2,960,000.00**
14. Was there an initial government estimate? If so, what amount?	☒ **NO** ☐ **YES, $**
15. Cost Determination Used- How did agency arrive at the estimate of expected costs?	**Obtained quotation from vendor.**
16. Explanation of Fair and Reasonable Price- Explain how agency determined that price is fair and reasonable	**Reagent rental contract to test for SCID mandated by DOH rules Chapter 122-15-1. No other FDA approved test kit exists.**
17. Documentation of Discussions with Contractor- How did agency document discussions with Contractor? Attach documentation to this request as applicable.	**Obtained sole source letter and price quote from vendor.**
18. Explanation of Need for or requirement placed on the State to acquire the goods or services	**Not entering into contract means that testing will not be able to be performed. If testing cannot be perfomed then this violates State rules and regulations regarding testing all newborn for Inborn Errors of Metabolism and other genetic disorders. Tests are mandated by rules and regulations of the DOH under Chapter 1200-15-1.**
19. Proposed contract impact on current State operations	**None**

Request Tracking #	–
20. Justification – Specifically explain why the goods or services should be acquired through the procurement method or contract type selected.	**To be compliant with State and DOH rules and regulations, testing for SCID must occur. This is the only FDA approved test kit that can be bought.**
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.	☐ NO ☐ 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	**Screening test mandated by DOH rules and regulations under Chapter 1200-15-1.**
26. Evidence of Contractor's experience & length of experience providing the goods or services to be procured.	**Contractor has been providing reagents by contract to the State of Tennessee for more than 10 years. Contractor has been in business for over 60 years providing newborn screening applications**
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.	☐ NO ☒ YES, **Method: Sole source reagent rental contract for En-LITE TREC to test for SCID** **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** **Contact: Jeanne Brunger**
28. Contractor selection process and efforts to identify reasonable, competitive, procurement alternatives	**Reagent rental contract This is the only FDA approved kit that can be purchased. There are no others.**
Signature Required for all Special Contract Requests	

Request Tracking #	–

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: 5 Mar 15

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

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 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.

3. 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.

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.

Estimated Funding New Contract Period	
1st 12 MONTHS	$592,000.00
2nd 12 MONTHS	$592,000.00
3rd 12 MONTHS	$592,000.00
4th 12 MONTHS	$592,000.00
5th 12 MONTHS	$592,000.00

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 (Days)

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

8. 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.

9. Firm Bid Price Period (Price Increase Allowed After Time Frame)

Prices quoted shall be firm for 365 days following the contract start date, except in the event an unexpected charge is imposed on the contractor holder by federal, state, county or city government entity during the term of the contract. The vendor/contractor may invoice the state for the imposed charge amount as long as it provides proof (invoice or statement, etc.) of the imposed charge to the user agency. The state shall also be advised of and receive the benefit of any price decrease in excess of five (5) percent automatically. The vendor/contractor holder must provide written price reduction information within ten (10) days of its effective date. Requests for price changes based on vendor/contractor's cost: Written requests for price changes based on vendor/contractor's actual cost for other than an imposed charge by federal, state, county, or city government entity after the firm price period shall be submitted in writing to the Central Procurement Office. Any increase shall be based on the vendor's/contractor's actual cost increase, may not constitute additional profit as shown in written cost documentation and must contain data establishing or supporting the general or industry wide nature of the change. At the option of the state, (1) request may be granted, (2) the contract may be canceled and awarded to the next low bidder, (3) the contract may be canceled and the commodity/service be re-advertised for award, or (4) continue the contract without change. The Central Procurement Office will accept or reject all such written requests within forty-five (45) working days of the date of receipt of complete and verified documentation. Approval of Price Increases: If approved, the Central Procurement Office will modify the contract to reflect the approved price increase and issue the revised contract. The vendor/ contractor shall honor all purchase orders dated prior to the approved price increase acceptance date at the original contract price. Approval of any price increase renews the firm price period. Price Increase Rejection: When the state rejects a request for a price increase, the vendor/ contractor will be notified in writing of the state's intention. If the contract is to be canceled, the vendor/contractor shall be notified of the cancellation date via certified mail. The vendor/ contractor will be required to honor all purchase orders that were prepared and dated prior to the date of the cancellation, if received by the vendor/contractor within a thirty (30) days following the date of the cancellation.

10. 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.

11. 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.

12. 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.

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. 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.

15. 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.

16. 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.

17. 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.

18. Award Criteria

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

Ability to Perform
Conformity to Specifications

19. 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

20. 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.

21. 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.

22. 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.

23. 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.

DRAFT

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)	**% 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) _____

PerkinElmer
For the Better

HUMAN HEALTH · ENVIRONMENTAL HEALTH

PerkinElmer Health Sciences.
Genetic Screening 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

January 15, 2015

Tennessee Department of Health
Laboratory Services
630 Hart Lane
Nashville, TN 37243

Attention: Chris Dorley

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. The following products are made by or for PerkinElmer Health Sciences, Inc. and are not sold through distributors in the USA. These products are only available from PerkinElmer Health Sciences, Inc.

3401-001U	EnLite™ Neonatal TREC kit
1420-0230	Victor EnLite™

Please feel free to contact the undersigned at 800-762-4000 with any questions.

Very truly yours,

Craig Cornut
PerkinElmer Health Sciences, Inc.
Diagnostics Customer Care

Specification for Neonatal TREC System for Newborn Screening 5 year reagent rental contract

Minimum Specifications for 100,000 tests per year

1. Assay must be FDA approved for screening for Severe Combined Immunodeficiency (SCID) by detection of T-cell reception excision circles (TREC).
2. Assay must be polymerase chain reaction (PCR) based combined with fluorescent detection of end product.
3. Assay must use dried blood spot as the specimen source.
4. All reagents necessary for performing analysis must be included in the test kit. Each kit should include:
    a. Reagents sufficient to analyze 384 reactions per kit (4 x 96 well reactions)
    b. Three levels of quality control ranging from normal to abnormal for SCID to assure run quality and sufficient QC to analyze in duplicate on each 96 well test plate
    c. Three levels of dried blood spot standards to analyze in triplicate on each 96 well test plate. Standards must be used to calculate patient results.
5. Vendor shall supply at least eight thermocyclers. Four specifically to support pre-amplification and four to support post-amplification.
6. Vendor shall supply 2 fluorescent readers that will read fluorescent end product from the test assay.
7. Fluorescent reader must be compatible with Lab software (Specimen Gate and NATUS) for generation of plate maps and result processing and reporting.
8. Vendor shall supply one pre-PCR hood with positive air flow with UV light.
9. Vendor shall supply one antistatic gun.
10. Vendor shall supply one barcode reader.
11. Other consumables to be supplied include:
    a. 96 well PCR plates, black with following quantity: 1300
    b. 4 pack replacement UV bulbs
    c. Replacement filters 1 pack
    d. Adhesive clear PCR seals: 2600
    e. 1.5 mm punch head for Panthera puncher
12. Turnaround time from the beginning of the analysis to results must be less than four hours.
13. Vendor shall provide training for a maximum of 3 laboratory personnel for 2 days either on site or at vendor location at no cost to the State of Tennessee.
14. Vendor shall be responsible for all maintenance of equipment associated with TREC assay and replacement of worn parts and repairs.
15. Vendor must provide toll free assistance for troubleshooting Monday through Saturday, 7 a.m. to 4:00 p.m. central standard time. Response must be within 24 hours of call and onsite response within 48 hours if phone assistance does not solve the problem.
16. Vendor to provide all installation of equipment, labor and manpower required to install instruments fully to operational stage.
17. Vendor to provide software support for integration of system with current Specimen Gate Software.
18. Vendor shall allow additional purchase of reagents and supplies necessary to conduct testing on an individual basis.
19. Vendor must provide at least 3 kits for evaluation for licensure specifications at no cost.

SPECIFICATIONS
Manual EnLite™ TREC System

Vendor to provide instrumentation, service and support to run the FDA cleared EnLite™ TREC kits.

Instruments, Accessories, Service, Software

A. Two (2) Manual EnLite™ TREC systems to include the following components:

- Victor EnLite
- Bio-RAD S1000™ Thermal Cycler
- Hood- PrePCR- Positive Airflow- UV Light
- Anti-Static Gun
- Barcode reader (for Workstation PC)

B. Installation:

- Vendor to provide all equipment, labor and manpower required to install instruments to fully operational stage

C. Training:

- Vendor to provide training for a maximum of 3 laboratory personnel for 2 days. No travel, hotel, or per diem charges will be paid by the state.

D. 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.

E. Maintenance:

- Vendor will be responsible for all repairs and preventive maintenance procedures on the instruments and accessories provided to run the EnLite™ TREC kits per the original vendor's maintenance manuals.
- The vendor will be responsible for parts and supplies 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 state will not be responsible for replacing the instruments in case of loss due to fire or theft.

F. Software

- The vendor will provide software support for the software required for integration with Specimen Gate Laboratory software, which is included in the annual contract and quarterly fee and at no additional charge based on the current Specimen Gate Laboratory contract.

Reagents

A. EnLite™ TREC kit

- Shall contain reagents for 4 plates per kit (384 tests)
- Shall include all materials necessary to run EnLite™ TREC manual method including controls
- Kit must be FDA cleared

Annual pricing shall include the cost of the following:

2 Manual EnLite TREC systems
103 EnLite TREC kits, vendor number 3401-001U

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HUMAN HEALTH | ENVIRONMENTAL HEALTH

PerkinElmer, Inc.
710 Bridgeport Avenue
Shelton, CT 06484-4794
USA

Phone 800 762 4200 x1 x2
Fax 203 762 4901
www.perkinelmer.com

BUDGET QUOTATION
EnLite™ Neonatal TREC System, Kits, Consumables and Service – Manual Method

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

January 15, 2015

Attn: Christine Dorley, Director Newborn Screening
Thomas Childs, Supervisor Newborn Screening
Nina Smith, Supervisor Newborn Screening

Pricing based on 82,000 births per year (100,000 specimens per year)
Term: 5 years

Quote Ref #	Quote Expires	FOB	Sales Representative	Terms
122714-1JB	Feb. 15, 2015	Boston, MA Shipping Charges Included	Jeanne Brunger Cell phone: 205 746 4113	Net 30

2 EnLite™ Neonatal TREC Systems with kits and consumables **Quarterly Fee (product code: NPNEO-AG)**	**$148,000**
Total per year	**$592,000**

The Laboratory will be billed a quarterly fee that will include reagents, instruments and service contract. The maximum limit of kits for the EnLite™ Neonatal TREC System that will be shipped during a contract year is listed as Base Quantity in Table I. The base quantity is calculated from the current State of Tennessee specimen rate (100,000 specimens per year) which includes repeat testing, such as due to the referral rate. For the purposes of this quote, the referral rate was determined to be less than 1% based on following published multicenter study: Kwan A, et al. *JAMA*. 2014;312(7):729-738. The base quantity can be adjusted between year 1 and year 2 of the contract if necessary to reflect actual usage during the first contract year. During the validation phase, kits will be provided. The EnLite™ Neonatal TREC kits and consumables will be shipped at no charge and will be included in the annual contract quantity and quarterly fee. The validation phase is expected to last approximately 1 month beginning 1 week after EnLite™ Neonatal TREC System training.

If additional kits are needed, the laboratory may purchase at the price listed in Table II. After the shipments in the 3rd quarter of the contract year, PerkinElmer will provide a report with the quantity of kits and shipping dates for each kit, the number of kits remaining in the base contract quantity, and an estimate of the number of kits the laboratory will need to purchase to complete the 4th quarter shipments. The price of the additional kits does not include instrument or service cost.

The instruments and accessories are listed in Table III. Service support, including regular preventative maintenance, is included in the annual contract and quarterly fee. Software required for integration with Specimen Gate Laboratory software is included in the annual contract and quarterly fee and at no additional charge based on the current Specimen Gate Laboratory contract.

Price Increases:
Prices for the quarterly fixed fee and additional kits will be firm for the first 2 contract terms (year 1 and year 2). There may be an increase on the renewals beginning year 3 of the contract. 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.

All reagents are currently FDA cleared and in use for Newborn Screening worldwide.

TABLE I: ANNUAL BASE QUANTITIES

Kit	Part #	Description	Quantity per contract year
TREC	3401-001U	EnLite™ Neonatal TREC kit (384 reactions, 4 x 96 reactions)	103
Consumables			
	US0206	4-pk of replacement UV bulbs	1
	US0208	Pack of 12 replacement pre-filters for AC632LFUVC or AC632TLFUVC	1
	3410-0010	EnLite 96-well PCR Plates, black (50 plates)	26
	3411-0010	EnLite Adhesive clear PCR seals (100 per pack)	26
	2081-2010	1.5 mm punch head for Panthera-Puncher™ 9	2

If additional kits and/or consumables are needed during the last quarter of the contract year, they may be purchased at the prices listed below.

TABLE II: PRICE OF ADDITIONAL KITS AND CONSUMABLES

Kit	Part #	Description	Price
TREC	3401-001U	EnLite™ Neonatal TREC kit (384 reactions, 4 x 96 reactions)	$623.00
Consumables			
	US0206	4-pk of replacement UV bulbs	180.00
	US0208	Pack of 12 replacement pre-filters for AC632LFUVC or AC632TLFUVC	150.00
	3410-0010	EnLite 96-well PCR Plates, black (50 plates)	291.00
	3411-0010	EnLite Adhesive clear PCR seals (100 per pack)	214.00

Notes:

- Shipping charges are included in price of the kit.

Table III: INSTRUMENTS AND ACCESSORIES

Part #	Description	Quantity per contract year
1420-0230	Victor EnLite	2
US0169	Bio-RAD S1000™ Thermal Cycler	8
US0173	Hood- PrePCR- Positive Airflow- UV Light	1
US0177	Anti-Static Gun	1
11700007	Barcode reader (for Workstation PC)	1

Notes: Specifications will be provided in a separate document.

Service support, including regular preventative maintenance, is included in the annual contract and quarterly fee.

Software required for integration with Specimen Gate Laboratory software is included in the annual contract and quarterly fee and at no additional charge based on the current Specimen Gate Laboratory contract.