



**STATE OF TENNESSEE  
DEPARTMENT OF HEALTH**  
ANDREW JOHNSON TOWER, 5TH FLOOR  
710 JAMES ROBERTSON PARKWAY  
NASHVILLE, TENNESSEE 37243

**BILL LEE**  
GOVERNOR

**LISA PIERCEY, MD, MBA, FAAP**  
COMMISSIONER

April 29, 2019

Krista Lee Carsner, Director  
Fiscal Review Committee  
Suite G-102, Cordell Hull Building  
425 5<sup>th</sup> Avenue North  
Nashville, TN 37243

Mike Perry, Chief Procurement Officer  
Central Procurement Office, Department of General Services  
312 Rosa L. Parks Avenue  
Nashville, TN 37243

Dear Director Carsner and CPO Perry:

The Department of Health, Division of Laboratory Services is requesting sole source approval to establish a multi-year contract (3 years with 2 options) for the purchase of reagents and rental of instruments required to perform Cell Free Fetal DNA mutation analysis testing. State law requires that all newborns be tested for inborn errors of metabolism and other genetic disorders, including Cystic Fibrosis.

Luminex is the only FDA-approved vendor that meets the requirements of Tennessee Code Annotated Section 68-5-401 and Tennessee Department of Health Rule Chapter 1200-15-01 and the recommendations of the Tennessee Genetics Advisory Committee regarding the appropriate amount of mutations. The total cost of the 3 year contract is \$473,184.00, and the total cost with the 2 options is \$788,640.00. The contract is funded by the collection of fees for newborn screening tests.

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 "Lisa Piercey".

Lisa Piercey, MD, MBA, FAAP  
Commissioner

Supplemental Documentation Required for  
Fiscal Review Committee

*Contact Name:	Richard Steece Paula Gibbs	*Contact Phone:	615-262-6300 615-262-6364		
*Presenter's name(s):	Richard Steece Paula Gibbs				
Edison Contract Number: <i>(if applicable)</i>		RFS Number: <i>(if applicable)</i>			
*Original or Proposed Contract Begin Date:	10/01/19	*Current or Proposed End Date:	09/30/24		
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:	05/01/19				
*Submitted Within Sixty (60) days:	Yes				
<i>If not, explain:</i>					
*Contract Vendor Name:	Luminex				
*Current or Proposed Maximum Liability:	\$788,640.00				
*Estimated Total Spend for Commodities:	\$788,640.00				
<b>*Current or Proposed Contract Allocation by Fiscal Year:</b> <b><i>(as Shown on Most Current Fully Executed Contract Summary Sheet)</i></b>					
FY:20	FY:21	FY:22	FY:23	FY24	FY25
\$157,728.00	\$157,728.00	\$157,728.00	\$157,728.00	\$92,008.00	\$65,720.00
<b>*Current Total Expenditures by Fiscal Year of Contract:</b> <b><i>(attach backup documentation from Edison)</i></b>					
FY:	FY:	FY:	FY:	FY	FY
\$	\$	\$	\$	\$	\$
<b>IF</b> Contract Allocation has been greater than Contract Expenditures, please give the reasons and explain where surplus funds were spent:			N/A		
<b>IF</b> surplus funds have been carried forward, please give the reasons and provide the authority for the carry forward provision:			N/A		
<b>IF</b> Contract Expenditures exceeded Contract Allocation, please give the			N/A		

## Supplemental Documentation Required for Fiscal Review Committee

reasons and explain how funding was acquired to pay the overage:			
<b>*Contract Funding Source/Amount:</b>			
State:		Federal:	
<i>Interdepartmental:</i>		<i>Other:</i>	100%
If " <i>other</i> " please define:		Fees collected from Newborn Screening testing	
If " <i>interdepartmental</i> " 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?		\$473,184.00 for the first 3 years, \$788,640.00 for the total 5 years. Cost was determined by previous usage and vendor quotation.	
*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.		There are no other vendors who can provide the reagents and instrumentation required to run this testing on all newborns. This system and reagents are the only FDA approved instrument and reagents meeting the Tennessee Genetics Advisory Committee guidelines.	

**TO:** Chris Salita, Director of Sourcing  
Kevin Bartels, Staff Attorney – Sourcing

**FROM:** Tara Roark, Sourcing Account Specialist

**DATE:** April 16, 2019

**SUBJECT:** Recommendation of Special Contract Request 34301-cy19-13245-(HL00000288)

Tara  
Roark

Digitally signed by Tara Roark  
DN: cn=Tara Roark, o=CPO,  
ou=General Services,  
email=Tara.Roark@tn.gov, c=US  
Date: 2019.04.16 08:19:02 -05'00'

Special Contract Request 34301-cy19-13245-(HL00000288) is a sole source request by the Department of Health for a rental contract with Luminex who will provide all reagents and instrumentation to perform Cell Free Fetal DNA (CF DNA) mutation analysis testing.

Luminex is the only FDA approved vendor that meets the requirements of Tennessee state law TCA 68-5-401. Other vendors do not offer the appropriate amount of mutations that the Tennessee Genetics Advisory Committee (GAC) requires or only offer a diagnostic kit rather than a screening kit.

I, Tara Roark, recommend approval of this sole source request.

**Chris Salita**

Digitally signed by Chris Salita  
DN: cn=Chris Salita, o=CPO, ou=32101,  
email=Chris.Salita@tn.gov, c=US  
Date: 2019.04.17 14:00:22 -05'00'

---

Director of Sourcing

Date

**Kevin C. Bartels**

Digitally signed by Kevin C. Bartels  
DN: cn=Kevin C. Bartels, o=CPO, ou=Legal,  
email=Kevin.C.Bartels@tn.gov, c=US  
Date: 2019.04.16 14:19:45 -05'00'

---

Staff Attorney – Sourcing

Date

# 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.

<p><b>APPROVED</b></p> <p><b>Michael F. Perry-CS</b></p> <p><small>Digitally signed by Michael F. Perry-CS DN: cn=Michael F. Perry-CS, o=CPO, ou=32101, email=Chris.Salita@tn.gov, c=US Date: 2019.04.17 14:00:38 -05'00'</small></p>	<p><b>APPROVED</b></p> <p><b>Bryan Chriske on behalf of Comptroller Justin P. Wilson</b></p> <p><small>Digitally signed by Bryan Chriske on behalf of Comptroller Justin P. Wilson Date: 2019.04.18 16:22:53 -05'00'</small></p>
<b>CHIEF PROCUREMENT OFFICER</b>	<b>DATE</b>
<b>COMPTROLLER OF THE TREASURY</b>	<b>DATE</b>

<b>Request Tracking #</b>	<b>HL00000288</b>
<b>1. Contracting Agency</b>	<b>Health</b>
<b>2. Type of Contract or Procurement Method</b>	<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 _____
<b>3. Requestor Contact Information</b>	<b>Christine Dorley</b> <b>630 Hart Lane</b> <b>Nashville, TN 37243</b> <b>615-262-6352</b>
<b>4. Brief Goods or Services Caption</b>	<b>Luminex CFDNA Reagent Rental</b>
<b>5. Description of the Goods or Services to be Acquired</b>	<b>Luminex will provide all reagents and instrumentation in a reagent rental contract to perform Cell Free Fetal DNA (CF DNA) mutation analysis testing.</b>
<b>6. Proposed Contractor</b>	<b>Luminex</b>

<b>Request Tracking #</b>	<b>HL00000288</b>
<b>7. Name &amp; Address of the Contractor's principal owner(s)</b> – NOT required for a TN state education institution	<b>Luminex</b> <b>12212 Technology Boulevard</b> <b>Austin, TX 78727</b> <b>Ede Brooks McCullough, RD, LDN</b> <b>737-704-1674</b> <b><a href="mailto:emccullough@luminexcorp.com">emccullough@luminexcorp.com</a></b>
<b>8. Proposed Contract Period – with ALL options to extend exercised</b> <i>The proposed contract start date shall follow the approval date of this request.</i>	<b>36 months + 2 options to renew</b>
<b>9. Strategic Technology Solutions (“STS”) Pre-Approval Endorsement Request</b> – information technology (N/A to THDA)	<input type="checkbox"/> Not Applicable <input checked="" type="checkbox"/> Attached
<b>10. eHealth Pre-Approval Endorsement Request</b> – health-related professional, pharmaceutical, laboratory, or imaging	<input checked="" type="checkbox"/> Not Applicable <input type="checkbox"/> Attached
<b>11. Human Resources Pre-Approval Endorsement Request</b> – contracts with an individual, state employee training, or services related to the employment of current or prospective state employees	<input checked="" type="checkbox"/> Not Applicable <input type="checkbox"/> Attached
<b>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.</b>	<input checked="" type="checkbox"/> NO <input type="checkbox"/> YES,
<b>13. Maximum Contract Cost – with ALL options to extend exercised</b>	<b>\$ 788,640.00</b>
<b>14. Was there an initial government estimate? If so, what amount?</b>	<input checked="" type="checkbox"/> NO <input type="checkbox"/> YES, \$
<b>15. Cost Determination Used-</b> How did agency arrive at the estimate of expected costs?	<b>Vendor Quote</b>
<b>16. Explanation of Fair and Reasonable Price-</b> Explain how agency determined that price is fair and reasonable	<b>Price was compared to previous CFDNA reagent rental contract (51181) that expires 9/30/19. The multi-year quotation offered by Luminex includes same pricing offered in 2016.</b>
<b>17. Documentation of Discussions with Contractor-</b> How did agency document discussions with Contractor? Attach documentation to this request as applicable.	<b>In person/ Via email</b>
<b>18. Explanation of Need for or requirement placed on the State to acquire the goods or services</b>	<b>Testing is required by state rules and regulations for the Department of Health (DOH) under chapter 1200-15-1 for all newborns for Inborn errors of metabolism and other genetic disorders including Cystic Fibrosis (CF).</b>
<b>19. Proposed contract impact on current State operations</b>	<b>The ability to test all newborns and comply with state law TCA 68-5-401.</b>

<b>Request Tracking #</b>	<b>HL00000288</b>
<b>20. Justification</b> – Specifically explain why the goods or services should be acquired through the procurement method or contract type selected.	Luminex is the only FDA approved vendor that meets the requirements of Tennessee state law TCA 68-5-401. Other vendors do not offer the appropriate amount of mutations that the Tennessee Genetics Advisory Committee (GAC) requires or only offer a diagnostic kit rather than a screening kit. The xTAG 39 Cystic Fibrosis (CFTR) kit offered by Luminex is a screening kit which provides information used for carrier testing in adults of reproductive age and in confirmatory testing in newborns and children. The kit is not indicated for use in fetal diagnostics but instead of for performing newborn screening; which directly supports chapter 1200-15-1. Luminex is the only vendor that has the good or service that meets the State's needs.
<b>For No Cost and Revenue Contracts Only</b>	
<b>21. What costs will the State incur as a result of this contract? If any, please explain.</b>	
<b>22. What is the total estimated revenue that the State would receive as a result of this contract?</b>	
<b>23. Could the State also contract with other parties interested in entering substantially the same agreement? Please explain.</b>	<input type="checkbox"/> NO <input type="checkbox"/> YES
<b>24. Summary of State responsibilities under proposed contract</b>	
<b>For Sole Source and Proprietary Procurements Only</b>	
<b>25. Evidence of Contractor's experience &amp; length of experience providing the goods or services to be procured.</b>	Luminex has been in business providing goods and services to the newborn screening community for over 20 years.
<b>26. 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.</b>	<input type="checkbox"/> NO <input checked="" type="checkbox"/> YES, Method: Sole Source Name/Address: Luminex 12212 Technology Boulevard Austin, TX 78727
<b>27. Contractor selection process and efforts to identify reasonable, competitive, procurement alternatives</b>	Luminex is the only FDA approved vendor that meets the requirements of Tennessee state law TCA 68-5-401.
<b>Signature Required for all Special Contract Requests</b>	

<b>Request Tracking #</b>	<b>HL00000288</b>
<b>Signature of Agency head or authorized designee, title of signatory, and date</b> (the authorized designee may sign his or her own name if indicated on the Signature Certification and Authorization document)	
<b>Lindsay Oliveras</b>	Digitally signed by Lindsay Oliveras DN: cn=Lindsay Oliveras, o=TN Dept. of Health, ou, email=lindsay.r.oliveras@tn.gov, c=US Date: 2019.04.08 15:00:39 -05'00'
Signature:	Date:



**Invitation to Bid (ITB)**  
For 34301 Luminex  
Event # XXXX

- 1.1. Section 1 -- Background Information
- 1.2. To establish a multi-year rental contract with Luminex who will provide all reagents and instrumentation to perform Cell Free Fetal DNA (CF DNA) mutation analysis testing.
- 1.3. **Accommodation for People with Disabilities.** Any individuals with disabilities who wish to participate in public meetings such as a scheduled pre-response conference or other scheduled function should contact the Solicitation Coordinator to discuss any auxiliary aids or services needed. Such contact should be made no less than three (3) business days prior to the public meeting to allow time for the Solicitation Coordinator to provide needed aids or services.
- 1.4. **Responses Due.** The response must be received by the State on or before the date and hour designated for the response opening. Responses that are submitted untimely shall be rejected.
- 1.5. Section 2 -- Award Criteria
- 1.6. **Single Award -- Lowest Cost.** A single contract will be awarded for all line items to the respondent whose response meets the requirements and criteria set forth in this ITB at the lowest cost.
- 1.7. Section 3 -- Standard Terms of the Solicitation
- 1.8. **Respondent Registration.** Pursuant to Tenn. Code Ann. § 4-56-105 all respondents must be registered prior to the issuance of a contract or a purchase order. Respondents can register online at the State of Tennessee Supplier Portal:  
  
[https://sso.edison.tn.gov/psp/paprd/SUPPLIER/SUPP/h/?tab=PAPP\\_GUEST](https://sso.edison.tn.gov/psp/paprd/SUPPLIER/SUPP/h/?tab=PAPP_GUEST)
- 1.9. **Respondent's Ability to Perform.** The State shall have the right to require evidence of the respondent's ability to perform the services or deliver the goods required

pursuant to the terms and conditions of this ITB.

- 1.10. **Quality of Workmanship and Materials.** Unit price responses are requested on goods or services that equal or exceed the specifications, unless the specifications limit the dimensions, brands, or model of goods or services. The absence of detailed specifications or the omission of detailed descriptions shall mean that only the best commercial practices and only first quality goods and workmanship shall be supplied.
- 1.11. **Performance.** The respondent who is awarded a contract will be responsible for delivering the goods or providing the services set out in this ITB. All goods or services are subject to inspection and evaluation by the State.
- 1.12. **Clarifications.** The State reserves the right to conduct clarifications or negotiations with one or more respondents. All communications, clarifications, and negotiations shall be conducted in a manner that is fair and transparent.
- 1.13. **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 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.
- 1.14. **Response Cancellation and Rejection.** The State may cancel this ITB in its entirety and reissue it in whole or in part.

The State may reject any or all responses in its sole discretion. Additionally, the State may reject a response that: (a) qualifies the offer to provide goods or services as required by this ITB; (b) proposes alternative goods or services unless expressly requested by this ITB; (c) involves collusion, consultation, communication, or agreement among respondents; (d) includes information the respondent knew or should have known was materially incorrect; or (e) does not comply with the terms, conditions, specifications, or performance requirements of this ITB.

After the State opens the responses, no price changes shall be permitted except pursuant to target pricing or best and final offer negotiations as specified in this ITB.

- 1.15. **Communications and Contacts.** Prospective respondents must direct communications concerning this ITB to the following person designated as the Solicitation Coordinator:

Tara Roark  
Department of General Services, CPO  
312 Rosa L Parks Avenue, 3rd Floor Tennessee Tower  
Nashville TN 37243-1102  
615-532-1837  
Tara.Roark@tn.gov

Unauthorized contact about this ITB with employees or officials of the State of Tennessee except as detailed in this ITB may result in disqualification from consideration under this procurement process. Notwithstanding the foregoing, respondents may alternatively contact:

Staff of the Governor's Office of Diversity Business Enterprise for assistance available to minority-owned, woman-owned, service-disabled veteran owned, businesses owned by persons with disabilities and small businesses as well as general, public information relating to this ITB (visit <https://www.tn.gov/general-services/procurement/central-procurement-office--cpo-/governor-s-office-of-diversity-business-enterprise--godbe--godbe-general-contacts.html> for contact information); and

The following individual designated by the State to coordinate compliance with the nondiscrimination requirements of the State of Tennessee, Title VI of the Civil Rights Act of 1964, the Americans with Disabilities Act, and associated federal regulations:

Helen Crowley  
Department of General Services, CPO  
312 Rosa L Parks Avenue, 3rd Floor Tennessee Tower  
Nashville, TN 37243-1102  
615-741-1035  
[Helen.Crowley@tn.gov](mailto:Helen.Crowley@tn.gov)

- 1.16. **Responses Submitted by Mail.** If submitting a response by mail: (1) all prices must be typed or written in ink on the "Line Details" portion of this ITB; (2) any corrections, erasures, or other alterations to prices must be initialed by the respondent; and (3) the response shall be manually signed by the respondent in ink. Each individual response 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 response opening date. Responses should be mailed in a properly labeled sealed envelope to the following address:

Bidder Services  
Department of General Services, CPO  
312 Rosa L Parks Avenue, 3rd Floor Tennessee Tower  
Nashville, TN 37243-1102.

Failure to comply with these requirements may result in rejection of the response.

- 1.17. **Models Included in Response.** All goods identified in the response must be new, of current manufacturer production, and must have been formally announced by the manufacturer or provider of services as being commercially available as of the date of response opening. Goods may include internal refurbished or reconditioned

components normally used in the manufacturing process and deemed and warranted and sold as new equipment by the manufacturer.

- 1.18. **Respondent Certification.** By signing or electronically submitting the response, the respondent agrees to the terms and conditions of this ITB and certifies that all goods or services included in the response meet or exceed the Scope or Specifications of this ITB. The respondent agrees that, if it is awarded a contract, it will deliver goods or services that meet or exceed the specifications in this ITB.
  
- 1.19. **Exceptions or New Terms or Conditions.** Exceptions to terms and conditions or new terms and conditions proposed by the respondent that vary from this ITB may, in the discretion of the State, render the response nonresponsive. A response deemed nonresponsive will not be considered for an award of a contract.
  
- 1.20. **Conflict of Interest.** The State shall not consider a response from an individual who is, or within the past six (6) months has been, a State employee. For purposes of this ITB:
  - a. An individual shall be deemed a State employee until such time as all compensation for salary, termination pay, and annual leave has been paid;
  - b. A contract with or a response from a company, corporation, or any other contracting entity in which a controlling interest is held by any State employee shall be considered to be a contract with or proposal from the employee; and
  - c. A contract with or a response from a company, corporation, or any other contracting entity that employs an individual who is, or within the past six (6) months has been, a State employee shall not be considered a contract with or a proposal from the employee and shall not constitute a prohibited conflict of interest.
  
- 1.21. **Specifications Govern.** Brands or model numbers identified in the specifications of this ITB are deemed to meet all written specifications. In the event of a conflict between specified brands and models and the written specifications, the conflict shall be resolved in favor of the written specifications.
  
- 1.22. **Firm Offer.** The response constitutes a firm offer that is irrevocable for ninety (90) days. An award of a contract shall, subject to necessary State approvals, be binding on the respondent without any further action by the respondent.
  
- 1.23. **F.O.B. Destination.** Respondent's prices shall include delivery of all items F.O.B. destination or as otherwise specified by the State.
  
- 1.24. **Tax Exemption.** The State of Tennessee is exempt from local, state, and federal excise taxes. These taxes shall not be included in respondent's prices. The successful respondent shall pay all taxes lawfully imposed on it with respect to any goods or services delivered in accordance with this ITB.

- 1.25. **Prompt Pay Discount.** Any prompt pay discounts offered by respondents shall be extended to all authorized users of the contract.
- 1.26. **Fixed Discount or Surcharge.** The percent discount or surcharge per line item must be fixed for the contract's term.
- 1.27. **On-site Inspection.** All respondents should visit the site to take exact measurements and examine the premises to become familiar with any problems or unusual circumstances. No allowances will be made by the State for errors in quotations due to any respondent not visiting the site prior to submitting their response. Respondents shall be responsible for their own measurements.
- 1.28. **Used Equipment.** When this ITB authorizes offers of used items, no used item is acceptable if serial numbers or any other manufacturer's identifying label or markings have been removed, obliterated, or changed in any way.
- 1.29. **Tennessee Contractor License.** Respondents shall be properly licensed as of the date it files a response to this ITB and shall provide evidence of compliance with all applicable provisions of the Contractors Licensing Act of 1994, Tenn. Code Ann. § 62-6-101, *et seq.* in providing the specified information within this ITB. Any response that does not comply with Tenn. Code Ann. § 62-6-119, when applicable, shall be rejected.
- 1.30. **Purchase of Materials for Highways or Roadways.** Respondents must comply with Tenn. Code Ann. § 54-5-135 when purchasing materials used for highway or road construction, resurfacing, or maintenance.
- 1.31. **Energy Star Products.** Any goods ordered by the State must be Energy Star certified and meet applicable Energy Star specifications for energy efficiency.
- 1.32. **Safety of Chemical Products.** All respondents awarded a contract must maintain, for all of its chemical products available under this Contract, a Safety Data Sheet ("SDS") on the chemical manufacturer's website. A site operated by or on behalf of the manufacturer or a relevant trade association is acceptable so long as the information is accessible to the public, free of charge.
- 1.33. **Professional Licensure.** All persons, agencies, firms, or other entities that provide legal or financial opinions, which a respondent provides for consideration and evaluation by the State as a part of a response to this ITB, shall be properly licensed to render such opinions. Upon submitting the response, the respondent (and respondent employees and subcontractors, as applicable) must hold all necessary or appropriate business or professional licenses to provide the goods or services as required by the contract. The State may require any respondent to submit evidence of proper licensure.
- 1.34. **Department of Revenue Registration.** Respondent must be registered with the Tennessee Department of Revenue for the collection of Tennessee sales and use tax. The State shall not award a contract unless the respondent provides proof of such registration or provides documentation from the Department of Revenue that the

Contractor is exempt from this registration requirement. The foregoing is a mandatory requirement of an award of a contract pursuant to this ITB. To register, please visit the Department of Revenue's Tennessee Taxpayer Access Point (TNTAP) website for Online Registration and the Vendor Contract Questionnaire. These resources are available at the following: <https://tntap.tn.gov/eservices/#1>

- 1.35. **Prohibition of Illegal Immigrants.** Any respondent awarded a contract shall comply with Tenn. Code Ann. § 12-3-309 and submit semi-annual attestations to the State.
  
- 1.36. **Inspection of Procurement File.** All respondents have the right to inspect the procurement file, prior to award, upon completion of the evaluation by the Central Procurement Office. Interested respondents should contact the Solicitation Coordinator following the response opening date or once the file is open for the seven (7) day inspection period. A "Notice of Intent to Award" letter will be sent to all respondents detailing which respondent(s) has been recommended for award and the evaluated award amount(s). Upon request, a reasonable opportunity to inspect the procurement file will be provided to the respondent.
  
- 1.37. **Protest by Respondent.** Pursuant to Tenn. Code Ann. § 12-3-514, any actual respondent 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: <https://www.tn.gov/generalservices/procurement.html>. If a written protest and a protest bond are not received by the end of the seven-day period to protest then the Solicitation Coordinator will proceed with the contract award.

## GOVERNOR'S OFFICE OF DIVERSITY BUSINESS ENTERPRISE

### Efforts to Achieve Diversity Business 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, service-disabled veteran-owned, disabled-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)

"Service-disabled veteran-owned business" means a service-disabled veteran-owned business located in the State of Tennessee that satisfies the criteria in Tenn. Code. Ann. § 12-3-1102(8). "Service-disabled veteran" means any person who served honorably in active duty in the armed forces of the United States with at least a twenty percent (20%) disability that is service-connected, i.e., the disability was incurred or aggravated in the line of duty in the active military, naval or air service.

#### Small Business Enterprise (SBE)

"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.

#### Disabled Business Enterprise (DSBE)

"Disabled Business Enterprise" means a business owned by a person with a disability that is a continuing, independent, for-profit business that performs a commercially useful function, and is at least fifty-one (51%) owned and controlled by one (1) or more persons with a disability, or, in the case of any publicly-owned business, at least fifty one percent (51%) of the stock of which is owned and controlled by one(1) or more persons with a disability and whose management and daily business operations are under the control of one (1) or more persons with a disability.

For additional program eligibility information, visit:

<https://www.tn.gov/generalservices/procurement/central-procurement-office--cpo-/governor-s-office-of-diversity-business-enterprise--godbe--/program-eligibility.html>

#### Instructions

As part of this Invitation to Bid, the respondent should complete the Diversity Utilization Plan below. 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:

<https://tn.diversitysoftware.com/FrontEnd/VendorSearchPublic.asp?TN=tn&XID=1215>

directory or by calling Go-DBE toll free at 866-894-5026.

**RESPONDENT'S DIVERSITY UTILIZATION 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 ___ DSBE ___ SDVBE ___ SBE		
Certifying Agency:		

**Estimated level of participation by DBEs if awarded a contract pursuant to this ITB:**

<b>Diversity Business Information</b> (List all subcontractors, joint-ventures, and suppliers)	<b>% of Contract</b>	<b>Estimated Amount</b>	<b>MBE/ WBE/ SDVBE/ SBE / DSBE Designation</b>	<b>Currently Certified (Yes or No)</b>
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 monthly report of participation in the performance of this Contract by small business enterprises and businesses owned by minorities, women, service-disabled veterans and persons with disabilities. Such reports shall be provided to the state of Tennessee Governor's Office of Diversity Business Enterprise in the TN Diversity Software available online at:

<https://tn.diversitysoftware.com/FrontEnd/StartCertification.asp?TN=tn&XID=9810>

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 Signatory \_\_\_\_\_



1.38. SCOPE:

- 1.39. **Scope.** The Contractor shall provide all goods or services and deliverables as required, described, and detailed in the Scope or Specifications set forth in the Invitation to Bid and meet all service and delivery timelines as specified by the Invitation to Bid.

1.40. Warranty Clauses:

- 1.41. **Warranty.** Contractor represents and warrants that the term of the warranty ("Warranty Period") shall be the greater of the Term of this Contract or any other warranty generally offered by Contractor, its suppliers, or manufacturers to customers of its goods or services. The goods or services provided under this Contract shall conform to the terms and conditions of this Contract throughout the Warranty Period. Any nonconformance of the goods or services to the terms and conditions of this Contract shall constitute a "Defect" and shall be considered "Defective." If Contractor receives notice of a Defect during the Warranty Period, then Contractor shall correct the Defect, at no additional charge. Contractor represents and warrants that the State is authorized to possess and use all equipment, materials, software, and deliverables provided under this Contract.

Contractor represents and warrants that all goods or services provided under this Contract shall be provided in a timely and professional manner, by qualified and skilled individuals, and in conformity with standards generally accepted in Contractor's industry.

If Contractor fails to provide the goods or services as warranted, then Contractor will re-provide the goods or services at no additional charge. If Contractor is unable or unwilling to re-provide the goods or services as warranted, then the State shall be entitled to recover the fees paid to Contractor for the Defective goods or services. Any exercise of the State's rights under this Section shall not prejudice the State's rights to seek any other remedies available under this Contract or applicable law.

- 1.42. **Inspection and Acceptance.** The State shall have the right to inspect all goods or services provided by Contractor under this Contract. If, upon inspection, the State determines that the goods or services are Defective, the State shall notify Contractor, and Contractor shall re-deliver the goods or provide the services at no additional cost to the State. If after a period of thirty (30) days following delivery of goods or performance of services the State does not provide a notice of any Defects, the goods or services shall be deemed to have been accepted by the State.

1.43. TERM OF CONTRACT:

- 1.44. Term of Contract.
- 1.45. This Contract shall be effective on October 01, 2019 ("Effective Date") and extend for a period of thirty-six (36) months after the Effective Date ("Term"). The State shall have no obligation for goods or services provided by the Contractor prior to the Effective Date. In no event, however, shall the maximum Term, including all renewals or extensions, exceed a total of sixty (60) months.
- 1.46. **Renewal Options.** This Contract may be renewed upon satisfactory completion of the Term. The State reserves the right to execute up to two (2) renewal options under the same terms and conditions, at the State's sole option. In no event, however, shall the maximum Term, including all renewals or extensions, exceed a total of sixty (60) months.
- 1.47. **Term Extension.** The State may extend the Term an additional period of time, not to exceed one hundred-eighty (180) days beyond the expiration date of this Contract, under the same terms and conditions, at the State's sole option.
- 1.48. PAYMENT TERMS AND CONDITIONS:
- 1.49. **Maximum Liability.** In no event shall the maximum liability of the State under this Contract exceed Written Dollar Amount (\$Number) ("Maximum Liability"). This Contract does not grant the Contractor any exclusive rights. The State does not guarantee that it will buy any minimum quantity of goods or services under this Contract. Subject to the terms and conditions of this Contract, the Contractor will only be paid for goods or services provided under this Contract after a purchase order is issued to Contractor by the State or as otherwise specified by this Contract.
- 1.50. **Compensation Firm.** The prices identified in this Contract, whether derived from an awarded published catalog, price list, price schedule, or other mutually agreed upon source shall constitute the entire compensation due the Contractor for all goods or services provided under this Contract regardless of the difficulty, materials or equipment required. The prices identified includes all applicable taxes, fees, overhead, and all other direct and indirect costs incurred or to be incurred by the Contractor.
- 1.51. **Travel Compensation.** The Contractor shall not be compensated or reimbursed for travel time, travel expenses, meals, or lodging.
- 1.52. **Invoice Requirements.** The Contractor shall invoice the State only for goods delivered and accepted by the State or services satisfactorily provided at the amounts stipulated in this Contract. Contractor shall submit invoices and necessary supporting documentation to the State Agency that requested goods or services no later than thirty (30) days after goods or services have been provided.
- a) Each invoice, on Contractor's letterhead, shall clearly and accurately detail all of the following information (calculations must be extended and totaled correctly):
1. Invoice number (assigned by the Contractor);

2. Invoice date;
3. Contract number (assigned by the State);
4. Purchase order number (assigned by the State);
5. Customer account name: The State of Tennessee;
6. Customer account number (assigned by the Contractor to the above-referenced Customer);
7. Contractor name;
8. Contractor Tennessee Edison supplier ID number;
9. Contractor contact for invoice questions (name, phone, or email);
10. Contractor remittance address;
11. Description of delivered goods or services provided and invoiced, including identifying information as applicable;
12. Number of delivered or completed units, increments, hours, or days as applicable, of each good or service invoiced;
13. Applicable payment methodology of each good or service invoiced;
14. Amount due for each compensable unit of good or service; and
15. Total amount due for the invoice period.

b) Contractor's invoices shall:

1. Only include charges for goods delivered or services provided as described in this Contract and in accordance with payment terms and conditions set forth in this Contract;
2. Only be submitted for goods delivered or services completed and shall not include any charge for future goods to be delivered or services to be performed;
3. Not include a line item for Contractor's taxes, which includes without limitation Contractor's sales and use tax, excise taxes, franchise taxes, real or personal Property taxes, or income taxes; and
4. Include shipping or delivery charges only as authorized in this Contract.

The timeframe for payment (or any discounts) begins only when the State is in receipt of an undisputed invoice that meets the minimum requirements of this Section.

- 1.53. **Payment of Invoice.** A payment by the State shall not prejudice the State's right to object to or question any payment, invoice, or other matter. A payment by the State shall not be construed as acceptance of goods delivered, any part of the services provided, or as approval of any amount invoiced.
- 1.54. **Invoice Reductions.** The Contractor's invoice shall be subject to reduction for amounts included in any invoice or payment that is determined by the State, on the basis of audits conducted in accordance with this Contract, to not constitute proper compensation for goods delivered or services provided.
- 1.55. **Deductions.** The State reserves the right to deduct from amounts, which are or shall become due and payable to the Contractor under this or any contract between the Contractor and the State of Tennessee, any amounts that are or shall become due and payable to the State of Tennessee by the Contractor.
- 1.56. **Prerequisite Documentation.** The Contractor shall not invoice the State under this Contract until the State has received the following, properly completed documentation.

- a) The Contractor shall complete, sign, and present to the State the "Authorization Agreement for Automatic Deposit Form" provided by the State. By doing so, the Contractor acknowledges and agrees that, once this form is received by the State, payments to the Contractor, under this or any other contract the Contractor has with the State of Tennessee, may be made by ACH; and
- b) The Contractor shall complete, sign, and return to the State the State-provided W-9 form. The taxpayer identification number on the W-9 form must be the same as the Contractor's Federal Employer Identification Number or Social Security Number referenced in the Contractor's Edison registration information.

1.57. MANDATORY TERMS AND CONDITIONS:

- 1.58. **Substitute Items Offered by the Contractor.** In the event that an awarded item is no longer being manufactured or is replaced by a functionally equivalent item with superior technological features to the item being replaced, Contractor may offer a substitute item ("Substitute"). The Substitute shall: (a) meet or exceed the functional, technical, and performance characteristics of the item being replaced; (b) not exceed the cost of the item being replaced by more than ten percent (10%); and (c) be available for order on the date Contractor requests to make the substitution. Contractor shall not make any substitutions for awarded items without the State's prior, written approval. Contractor shall submit any proposed substitutions to the Central Procurement Office and include sufficient information to show that criteria (a) -- (c) above are met. The Central Procurement Office may request sample Substitutes for inspection or testing.
- 1.59. **Purchase Order Release.** Agency submission of a purchase order to Contractor authorizes Contractor to deliver goods or provide services.
- 1.60. **Delivery.** Contractor shall provide all goods or services as required and described in this Contract and shall meet all service and delivery timelines specified in this Contract. All quotations shall be F.O.B. destination.
- 1.61. **Required Approvals.** The State is not bound by this Contract until it is duly approved by the Parties and all appropriate State officials in accordance with applicable Tennessee laws and regulations. Depending upon the specifics of this Contract, this may include approvals by the Commissioner of Finance and Administration, the Commissioner of Human Resources, the Comptroller of the Treasury, and the Chief Procurement Officer. Approvals shall be evidenced by a signature or electronic approval.
- 1.62. **Communications and Contacts.** All instructions, notices, consents, demands, or other communications required or contemplated by this Contract shall be in writing and shall be made by certified, first class mail, return receipt requested and postage prepaid, by overnight courier service with an asset tracking system, or by email. All communications, regardless of method of transmission, shall be addressed to the respective party at the appropriate mailing address or email address as stated below or any other address provided in writing by a party.

The Contractor:

Contractor  
Contractor's Contact Name & Title  
Address  
Email Address  
Telephone Number

State of Tennessee:

Karen Olive  
Department of Health  
710 James Robertson Parkway, Andrew Johnson Tower, 5th Floor  
Nashville TN 37243  
615-253-5686  
Karen.Olive@tn.gov

All instructions, notices, consents, demands, or other communications shall be considered effective upon receipt or recipient confirmation as may be required.

- 1.63. **Modification and Amendment.** This Contract may be modified only by a written amendment signed by all parties and approved by all applicable State officials.
- 1.64. **Subject to Funds Availability.** The Contract is subject to the appropriation and availability of State or federal funds. In the event that the funds are not appropriated or are otherwise unavailable, the State reserves the right to terminate this Contract upon written notice to the Contractor. The State's exercise of its right to terminate this Contract shall not constitute a breach of Contract by the State. Upon receipt of the written notice, the Contractor shall cease all work associated with the Contract. If the State terminates this Contract due to lack of funds availability, the Contractor shall be entitled to compensation for all conforming goods requested and accepted by the State and for all satisfactory and authorized services completed as of the termination date. Should the State exercise its right to terminate this Contract due to unavailability of funds, the Contractor shall have no right to recover from the State any actual, general, special, incidental, consequential, or any other damages of any description or amount.
- 1.65. **Termination for Convenience.** The State may terminate this Contract for convenience without cause for any reason. The State's election to terminate this Contract for convenience shall be effective upon the date specified and shall not be deemed a breach of contract by the State. The Contractor shall be entitled to compensation for all conforming goods delivered and accepted by the State or for satisfactory, authorized services completed as of the termination date. In no event shall the State be liable to the Contractor for compensation for any good or service that has not been provided, nor shall the Contractor be relieved of any liability to the State for any damages or claims arising under this Contract.
- 1.66. **Termination for Cause.** If the Contractor fails to properly perform its obligations under this Contract in a timely or proper manner, or if the Contractor materially violates any terms of this Contract ("Breach Condition"), the State shall have the right to immediately terminate the Contract and withhold payments in excess of compensation for completed services or provided goods. Notwithstanding the above, the contractor shall not be relieved of liability to the State for damages sustained by virtue of any Breach Condition and the State may seek other remedies allowed at law or in equity

for breach of this Contract.

1.67. **Assignment and 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 the prior written approval of the State. Notwithstanding any use of the approved subcontractors, the Contractor shall be the prime contractor and responsible for compliance with all terms and conditions of this Contract. The State reserves the right to request additional information or impose additional terms and conditions before approving an assignment of this Contract in whole or in part or the use of subcontractors in fulfilling the Contractor's obligations under this Contract.

1.68. **Conflicts of Interest.** The Contractor warrants that no part of the Contractor's compensation shall be paid directly or indirectly to an employee or official of the State of Tennessee as wages, compensation, or gifts in exchange for acting as an officer, agent, employee, subcontractor, or consultant to the Contractor in connection with any work contemplated or performed under this Contract.

The Contractor acknowledges, understands, and agrees that this Contract shall be null and void if the Contractor is, or within the past six (6) months has been, an employee of the State of Tennessee or if the Contractor is an entity in which a controlling interest is held by an individual who is, or within the past six (6) months has been, an employee of the State of Tennessee.

1.69. **Nondiscrimination.** The Contractor hereby agrees, warrants, and assures that no person shall be excluded from participation in, be denied benefits of, or be otherwise subjected to discrimination in the performance of this Contract or in the employment practices of the Contractor on the grounds of handicap or disability, age, race, creed, color, religion, sex, national origin, or any other classification protected by federal or state law. The Contractor shall, upon request, show proof of nondiscrimination and shall post in conspicuous places, available to all employees and applicants, notices of nondiscrimination.

1.70. **Prohibition of Illegal Immigrants.** The requirements of Tenn. Code Ann. § 12-3-309 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.

- a) The Contractor agrees that the Contractor shall not knowingly utilize the services of an illegal immigrant in the performance of this Contract and shall not knowingly utilize the services of any subcontractor who will utilize the services of an illegal immigrant in the performance of this Contract. The Contractor shall reaffirm this attestation, in writing, by submitting to the State a completed and signed copy of the document at: <https://www.tn.gov/generalservices/procurement/central-procurement-office--cpo-/supplier-information-.html>, semi-annually during the Term. If the Contractor is a party to more than one contract with the State, the Contractor may submit one attestation that applies to all contracts with the State. All Contractor attestations shall be maintained by the Contractor and made available to State officials upon request.
- b) Prior to the use of any subcontractor in the performance of this Contract, and semi-annually thereafter, during the Term, the Contractor shall obtain and retain a current, written attestation that the subcontractor shall not knowingly utilize the services of an

illegal immigrant to perform work under this Contract and shall not knowingly utilize the services of any subcontractor who will utilize the services of an illegal immigrant to perform work under this Contract. Attestations obtained from subcontractors shall be maintained by the Contractor and made available to State officials upon request.

- c) The Contractor shall maintain records for all personnel used in the performance of this Contract. Contractor's records shall be subject to review and random inspection at any reasonable time upon reasonable notice by the State.
  - d) The Contractor understands and agrees that failure to comply with this section will be subject to the sanctions of Tenn. Code Ann. § 12-3-309 for acts or omissions occurring after its effective date.
  - e) For purposes of this Contract, "illegal immigrant" shall be defined as any person who is not: (i) a United States citizen; (ii) a Lawful Permanent Resident; (iii) a person whose physical presence in the United States is authorized; (iv) allowed by the federal Department of Homeland Security and who, under federal immigration laws or regulations, is authorized to be employed in the U.S.; or (v) is otherwise authorized to provide services under the Contract.
- 1.71. **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.
- 1.72. **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.
- 1.73. **Progress Reports.** The Contractor shall submit brief, periodic, progress reports to the State as requested.
- 1.74. **Strict Performance.** Failure by any Party to this Contract to require, in any one or more cases, the strict performance of any of the terms, covenants, conditions, or provisions of this Contract shall not be construed as a waiver or relinquishment of any term, covenant, condition, or provision. No term or condition of this Contract shall be held to be waived, modified, or deleted except by a written amendment signed by the Parties.
- 1.75. **Independent Contractor.** The parties shall not act as employees, partners, joint ventures, or associates of one another. The parties are independent contracting entities. Nothing in this Contract shall be construed to create an employer/employee relationship or to allow either party to exercise control or direction over the manner or method by which the other transacts its business affairs or provides its usual services. The employees or agents of one party are not employees or agents of the other party.

- 1.76. **Patient Protection and Affordable Care Act.** The Contractor agrees that it will be responsible for compliance with the Patient Protection and Affordable Care Act ("PPACA") with respect to itself and its employees, including any obligation to report health insurance coverage, provide health insurance coverage, or pay any financial assessment, tax, or penalty for not providing health insurance. The Contractor shall indemnify the State and hold it harmless for any costs to the State arising from contractor's failure to fulfill its PPACA responsibilities for itself or its employees.
- 1.77. **Limitation of State's Liability.** The State shall have no liability except as specifically provided in this Contract. In no event will the State be liable to the Contractor or any other party for any lost revenues, lost profits, loss of business, decrease in the value of any securities or cash position, time, money, goodwill, or any indirect, special, incidental, punitive, exemplary or consequential damages of any nature, whether based on warranty, contract, statute, regulation, tort (including but not limited to negligence), or any other legal theory that may arise under this Contract or otherwise. Notwithstanding anything else herein, the State's total liability under this Contract (including without limitation any exhibits, schedules, amendments or other attachments to the Contract) or otherwise shall under no circumstances exceed the Maximum Liability. This limitation of liability is cumulative and not per incident.
- 1.78. **Limitation of Contractor's Liability.** In accordance with Tenn. Code Ann. § 12-3-701, the Contractor's liability for all claims arising under this Contract shall be limited to an amount equal to two (2) times the Maximum Liability amount and as may be amended. Except as set forth below, in no event will the Contractor be liable to the State or any other party for any lost revenues, lost profits, loss of business, decrease in the value of any securities or cash position, time, money, goodwill, or any indirect, special, incidental, punitive, exemplary or consequential damages of any nature, whether based on warranty, contract, statute, regulation, tort (including but not limited to negligence), or any other legal theory that may arise under this Contract or otherwise. PROVIDED THAT in no event shall this Section limit the liability of the Contractor for: (i) intellectual property or any Contractor indemnity obligations for infringement for third-party intellectual property rights; (ii) any claims covered by any specific provision in the Contract providing for liquidated damages; or (iii) any claims for intentional torts, criminal acts, fraudulent conduct, or acts or omissions that result in personal injuries or death.
- 1.79. **Hold Harmless.** 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' fees, court costs, expert witness fees, and other litigation expenses for the State to enforce the terms of this Contract.

In the event of any suit or claim, the Parties shall give each other immediate notice and provide all necessary assistance to respond. The failure of the State to give notice shall only relieve the Contractor of its obligations under this Section to the extent that the Contractor can demonstrate actual prejudice arising from the failure to give notice. This Section shall not grant the Contractor, through its attorneys, the right to represent the State in any legal matter, as the right to represent the State is governed by Tenn.

Code Ann. § 8-6-106.

- 1.80. **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"). The obligations set forth in this Section shall survive the termination of this Contract.
- 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 the information without entering into a business associate agreement or signing another document.

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.

- 1.81. **Tennessee Consolidated Retirement System.** Subject to statutory exceptions contained in Tenn. Code Ann. §§ 8-36-801, et seq., the law governing the Tennessee Consolidated Retirement System ("TCRS"), provides that if a retired member of TCRS, or of any superseded system administered by TCRS, or of any local retirement fund established under Tenn. Code Ann. §§ 8-35-101, et seq., accepts State employment, the member's retirement allowance is suspended during the period of the employment. Accordingly and notwithstanding any provision of this Contract to the contrary, the Contractor agrees that if it is later determined that the true nature of the working relationship between the Contractor and the State under this Contract is that of "employee/employer" and not that of an independent contractor, the Contractor, if a retired member of TCRS, may be required to repay to TCRS the amount of retirement benefits the Contractor received from TCRS during the Term.
- 1.82. **Tennessee Department of Revenue Registration.** The Contractor shall comply with all applicable registration requirements contained in Tenn. Code Ann. §§ 67-6-601 -- 608. Compliance with applicable registration requirements is a material requirement of this Contract.
- 1.83. **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.

- 1.84. **Force Majeure.** "Force Majeure Event" means fire, flood, earthquake, elements of nature or acts of God, wars, riots, civil disorders, rebellions or revolutions, acts of terrorism or any other similar cause beyond the reasonable control of the Party except to the extent that the non-performing Party is at fault in failing to prevent or causing the default or delay, and provided that the default or delay cannot reasonably be circumvented by the non-performing Party through the use of alternate sources, workaround plans or other means. A strike, lockout or labor dispute shall not excuse either Party from its obligations under this Contract. Except as set forth in this Section, any failure or delay by a Party in the performance of its obligations under this Contract arising from a Force Majeure Event is not a default under this Contract or grounds for termination. The non-performing Party will be excused from performing those obligations directly affected by the Force Majeure Event, and only for as long as the Force Majeure Event continues, provided that the Party continues to use diligent, good faith efforts to resume performance without delay. The occurrence of a Force Majeure Event affecting Contractor's representatives, suppliers, subcontractors, customers or business apart from this Contract is not a Force Majeure Event under this Contract. Contractor will promptly notify the State of any delay caused by a Force Majeure Event (to be confirmed in a written notice to the State within one (1) day of the inception of the delay) that a Force Majeure Event has occurred, and will describe in reasonable detail the nature of the Force Majeure Event. If any Force Majeure Event results in a delay in Contractor's performance longer than forty-eight (48) hours, the State may, upon notice to Contractor: (a) cease payment of the fees for the affected obligations until Contractor resumes performance of the affected obligations; or (b) immediately terminate this Contract or any purchase order, in whole or in part, without further payment except for fees then due and payable. Contractor will not increase its charges under this Contract or charge the State any fees other than those provided for in this Contract as the result of a Force Majeure Event.

- 1.85. **State and Federal Compliance.** The Contractor shall comply with all State and federal laws and regulations applicable to Contractor in the Contractor's performance of this Contract.
- 1.86. **Governing Law.** This Contract shall be governed by and construed in accordance with the laws of the State of Tennessee, without regard to its conflict or choice of law rules. The Tennessee Claims Commission or the state or federal courts in Tennessee shall be the venue for all claims, disputes, or disagreements arising under this Contract. The Contractor acknowledges and agrees that any rights, claims, or remedies against the State of Tennessee or its employees arising under this Contract shall be subject to and limited to those rights and remedies available under Tenn. Code Ann. §§ 9-8-101 -- 408.
- 1.87. **Entire Agreement.** This Contract is complete and contains the entire understanding between the parties relating to its subject matter, including all the terms and conditions of the parties' agreement. This Contract supersedes any and all prior understandings, representations, negotiations, and agreements between the parties, whether written or oral.
- 1.88. **Severability.** If any terms and conditions of this Contract are held to be invalid or unenforceable as a matter of law, the other terms and conditions of this Contract shall not be affected and shall remain in full force and effect. The terms and conditions of this Contract are severable.
- 1.89. **Headings.** Section headings of this Contract are for reference purposes only and shall not be construed as part of this Contract.
- 1.90. **Incorporation of Additional Documents.** Each of the following documents is included as a part of this Contract by reference. In the event of a discrepancy or ambiguity regarding the Contractor's duties, responsibilities, and performance under this Contract, these items shall govern in order of precedence below:
- a) any amendment to this Contract, with the latter in time controlling over any earlier amendments;
  - b) this Contract with any attachments or exhibits (excluding the items listed at subsections c. through f., below);
  - c) any clarifications of or addenda to the Contractor's response seeking this Contract;
  - d) the Invitation to Bid, as may be amended, requesting responses in competition for this Contract;
  - e) any technical specifications provided to respondents during the procurement process to award this Contract; and,
  - f) the Contractor's response seeking this Contract.
- 1.91. **Iran Divestment Act.** The requirements of Tenn. Code Ann. § 12-12-101 et.seq., addressing contracting with persons with investment activities in Iran, shall be a material provision of this Contract. The Contractor agrees, under penalty of perjury,

that to the best of its knowledge and belief that it is not on the list created pursuant to Tenn. Code Ann. § 12-12-106.

1.92. Insurance Requirements:

- 1.93. **Insurance.** Contractor shall provide the State a certificate of insurance ("COI") evidencing the coverages and amounts specified below. The COI shall be provided ten (10) business days prior to the Effective Date and again upon renewal or replacement of coverages required by this Contract. If insurance expires during the Term, the State must receive a new COI at least thirty (30) calendar days prior to the insurance's expiration date. If the Contractor loses insurance coverage, does not renew coverage, or for any reason becomes uninsured during the Term, the Contractor shall notify the State immediately.

The COI shall be on a form approved by the Tennessee Department of Commerce and Insurance ("TDCI") and signed by an authorized representative of the insurer. The COI shall list each insurer's national association of insurance commissioners (also known as NAIC) number or federal employer identification number and list the State of Tennessee, Risk Manager, 312 Rosa L. Parks Ave., 3rd floor Central Procurement Office, Nashville, TN 37243 in the certificate holder section. At any time, the State may require the Contractor to provide a valid COI detailing coverage description; insurance company; policy number; exceptions; exclusions; policy effective date; policy expiration date; limits of liability; and the name and address of insured. The Contractor's failure to maintain or submit evidence of insurance coverage is considered a material breach of this Contract.

If the Contractor desires to self-insure, then a COI will not be required to prove coverage. In place of the COI, the Contractor must provide a certificate of self-insurance or a letter on the Contractor's letterhead detailing its coverage, liability policy amounts, and proof of funds to reasonably cover such expenses. Compliance with Tenn. Code Ann. § 50-6-405 and the rules of the TDCI is required for the Contractor to self-insure workers' compensation.

All insurance companies must be: (a) acceptable to the State; (b) authorized by the TDCI to transact business in the State of Tennessee; and (c) rated A- VII or better by A. M. Best. The Contractor shall provide the State evidence that all subcontractors maintain the required insurance or that the subcontractors are included under the Contractor's policy.

The Contractor agrees to name the State as an additional insured on any insurance policies with the exception of workers' compensation (employer liability) and professional liability (errors and omissions) ("Professional Liability") insurance. Also, all policies shall contain an endorsement for a waiver of subrogation in favor of the State.

The deductible and any premiums are the Contractor's sole responsibility. Any deductible over fifty thousand dollars (\$50,000) must be approved by the State. The Contractor agrees that the insurance requirements specified in this Section do not reduce any liability the Contractor has assumed under this Contract including any indemnification or hold harmless requirements.

The State agrees that it shall give written notice to the Contractor as soon as practicable after the State becomes aware of any claim asserted or made against the State, but in no event later than thirty (30) calendar days after the State becomes aware of such claim. The failure of the State to give notice shall only relieve the Contractor of its obligations under this Section to the extent that the Contractor can

demonstrate actual prejudice arising from the failure to give notice. This Section shall not grant the Contractor or its insurer, through its attorneys, the right to represent the State in any legal matter, as the right to represent the State is governed by Tenn. Code Ann. § 8-6-106.

All coverage required shall be on a primary basis and noncontributory with any other insurance coverage or self-insurance carried by the State. The State reserves the right to amend or require additional endorsements, types of coverage, and higher or lower limits of coverage depending on the nature of the work. Purchases or contracts involving any hazardous activity or equipment, tenant, concessionaire and lease agreements, alcohol sales, cyber-liability risks, environmental risks, special motorized equipment, or property may require customized insurance requirements (e.g. umbrella liability insurance) in addition to the general requirements listed below.

#### 1.94. Workers' Compensation and Employer Liability Insurance.

- a) For Contractors statutorily required to carry workers' compensation and employer liability insurance, the Contractor shall maintain:
  - b) Workers' compensation and employer liability insurance in the amounts required by appropriate state statutes; or
  - c) In an amount not less than one million dollars (\$1,000,000) including employer liability of one million dollars (\$1,000,000) per accident for bodily injury by accident, one million dollars (\$1,000,000) policy limit by disease, and one million dollars (\$1,000,000) per employee for bodily injury by disease.
- d) If the Contractor certifies that it is exempt from the requirements of Tenn. Code Ann. §§ 50-6-101 -- 103, then the Contractor shall furnish written proof of such exemption for one or more of the following reasons:
  1. The Contractor employees fewer than five (5) employees;
  2. The Contractor is a sole proprietor;
  3. The Contractor is in the construction business or trades with no employees;
  4. The Contractor is in the coal mining industry with no employees;
  5. The Contractor is a state or local government; or
  6. The Contractor self-insures its workers' compensation and is in compliance with the TDCI rules and Tenn. Code Ann. § 50-6-405.

#### 1.95. Commercial General Liability Insurance.

- a) The Contractor shall maintain commercial general liability insurance, which shall be written on an Insurance Services Office, Inc. (also known as ISO) occurrence form (or a substitute form providing equivalent coverage) and shall cover liability arising from property damage, premises/operations, independent contractors, contractual liability, completed operations/products, personal and advertising injury, and liability assumed under an insured contract (including the tort liability

of another assumed in a business contract).

- b) The Contractor shall maintain bodily injury/property damage with a combined single-limit not less than one million dollars (\$1,000,000) per occurrence and two million dollars (\$2,000,000) aggregate for bodily injury and property damage, including products and completed operations coverage with an aggregate limit of at least two million dollars (\$2,000,000).

1.96. **Automobile Liability Insurance.** The Contractor shall maintain automobile liability insurance which shall cover liability arising out of any automobile (including owned, leased, hired, and non-owned automobiles). The Contractor shall maintain bodily injury/property damage with a limit not less than one million dollars (\$1,000,000) per occurrence or combined single limit.

1.97. Professional Liability Insurance.

- a) Professional liability insurance shall be written on an occurrence basis. This coverage may be written on a claims-made basis but must include an extended reporting period or "tail coverage" of at least two (2) years after the Term;
- b) Any professional liability insurance policy shall have a limit not less than one million dollars (\$1,000,000) per claim and two million dollars (\$2,000,000) in the aggregate; and
- c) If the Contract involves the provision of services by medical professionals, a policy limit not less than two million (\$2,000,000) per claim and three million dollars (\$3,000,000) in the aggregate for medical malpractice insurance.

1.98. **Major Procurement Contract Sales and Use Tax.** Pursuant to Tenn. Code Ann. § 4-39-102 and to the extent applicable, the Contractor and the Contractor's subcontractors shall remit sales and use taxes on the sales of goods or services that are made by the Contractor or the Contractor's subcontractors and that are subject to tax.

1.99. **Confidentiality of Records.** Strict standards of confidentiality of records and information shall be maintained in accordance with applicable state and federal law. All material and information, regardless of form, medium or method of communication, provided to the Contractor by the State or acquired by the Contractor on behalf of the State that is regarded as confidential under state or federal law shall be regarded as "Confidential Information." Nothing in this Section shall permit Contractor to disclose any Confidential Information, regardless of whether it has been disclosed or made available to the Contractor due to intentional or negligent actions or inactions of agents of the State or third parties. Confidential Information shall not be disclosed except as required or permitted under state or federal law. Contractor shall take all necessary steps to safeguard the confidentiality of such material or information in conformance with applicable state and federal law.

The obligations set forth in this Section shall survive the termination of this Contract.

1.100. SPECIAL TERMS AND CONDITIONS:

- 1.101. **Conflicting Terms and Conditions.** Should any of these special terms and conditions conflict with any other terms and conditions of this Contract, the special terms and conditions shall be subordinate to the Contract's other terms and conditions.
- 1.102. **Prohibited Advertising or Marketing.** The Contractor shall not suggest or imply in advertising or marketing materials that Contractor's goods or services are endorsed by the State. The restrictions on Contractor advertising or marketing materials under this Section shall survive the termination of this Contract.
- 1.103. **Personally Identifiable Information.** While performing its obligations under this Contract, Contractor may have access to Personally Identifiable Information held by the State ("PII"). For the purposes of this Contract, "PII" includes "Nonpublic Personal Information" as that term is defined in Title V of the Gramm-Leach-Bliley Act of 1999 or any successor federal statute, and the rules and regulations thereunder, all as may be amended or supplemented from time to time ("GLBA") and personally identifiable information and other data protected under any other applicable laws, rule or regulation of any jurisdiction relating to disclosure or use of personal information ("Privacy Laws"). Contractor agrees it shall not do or omit to do anything which would cause the State to be in breach of any Privacy Laws. Contractor shall, and shall cause its employees, agents and representatives to: (i) keep PII confidential and may use and disclose PII only as necessary to carry out those specific aspects of the purpose for which the PII was disclosed to Contractor and in accordance with this Contract, GLBA and Privacy Laws; and (ii) implement and maintain appropriate technical and organizational measures regarding information security to: (A) ensure the security and confidentiality of PII; (B) protect against any threats or hazards to the security or integrity of PII; and (C) prevent unauthorized access to or use of PII. Contractor shall immediately notify State: (1) of any disclosure or use of any PII by Contractor or any of its employees, agents and representatives in breach of this Contract; and (2) of any disclosure of any PII to Contractor or its employees, agents and representatives where the purpose of such disclosure is not known to Contractor or its employees, agents and representatives. The State reserves the right to review Contractor's policies and procedures used to maintain the security and confidentiality of PII and Contractor shall, and cause its employees, agents and representatives to, comply with all reasonable requests or directions from the State to enable the State to verify and/or procure that Contractor is in full compliance with its obligations under this Contract in relation to PII. Upon termination or expiration of the Contract or at the State's direction at any time in its sole discretion, whichever is earlier, Contractor shall immediately return to the State any and all PII which it has received under this Contract and shall destroy all records of such PII.

The Contractor shall report to the State any instances of unauthorized access to or potential disclosure of PII in the custody or control of Contractor ("Unauthorized Disclosure") that come to the Contractor's attention. Any such report shall be made by the Contractor within twenty-four (24) hours after the Unauthorized Disclosure has come to the attention of the Contractor. Contractor shall take all necessary measures to halt any further Unauthorized Disclosures. The Contractor, at the sole discretion of the State, shall provide no cost credit monitoring services for individuals whose PII was affected by the Unauthorized Disclosure. The Contractor shall bear the cost of notification to all individuals affected by the Unauthorized Disclosure, including individual letters and public notice. The remedies set forth in this Section are not exclusive and are in addition to any claims or remedies available to this State under this Contract or otherwise available at law.

- 1.104. **Unencumbered Personnel.** The Contractor shall not restrict its employees, agents, subcontractors or principals who perform services for the State under this Contract from performing the same or similar services for the State after the termination of this Contract, either as a State employee, an independent contractor, or an employee, agent, subcontractor or principal of another contractor with the State.
- 1.105. **Liens, Encumbrances and Title.** The Contractor owns and has good and marketable title to, and legal ownership of the goods, free and clear of any and all liens, security interests, pledges, mortgages, charges, limitations, claims, restrictions, rights of first refusal, rights of first offer, rights of first negotiation or other encumbrances of any kind or nature (collectively, "Encumbrances"). Upon delivery, without exception, the State will acquire from the Contractor legal and beneficial ownership of, good and marketable title to, and all rights to the goods to be sold to the State by the Contractor, free and clear of all Encumbrances. The Contractor shall, within ten (10) days after delivery deliver to the State if required by applicable law to establish or show evidence of ownership, any and all documents or certificates required to establish or show evidence of the State's ownership in the goods.



## Information Technology Services Division Pre-Approval Endorsement Request

**TO :** Scott Creel,  
ITSD Contract Services  
Phone Number: 615-770-1152  
E-mail : [Scott.Creel@tn.gov](mailto:Scott.Creel@tn.gov)

**FROM :** Division Submitter's Name Kevin Woods  
Phone Number: (615) 262-6320  
E-mail Address: Kevin.Woods@tn.gov

**DATE :** MM/DD/YYYY 04/15/2019

**RE :** Request for ITSD Pre-Approval Review and Endorsement

**Applicable RFS or Purchase Requisition #: Requisition # 0000186558**

**ITSD Endorsement Signature & Date:**

**Mike Newman (Scott Creel)**

Digitally signed by Mike Newman (Scott Creel)  
DN: cn=Mike Newman (Scott Creel), o=TDH, ou=ITSD,  
email=Mike.Newman@tn.gov, c=US  
Date: 2019.04.15 08:08:24 -05'00'

**Chief Information Officer**

**Date**

*NOTE: Proposed contract/grant support is applicable to the subject IT service technical merit.*

Department of Health's Information Technology Services Division (ITSD) Pre-approval Endorsement Request is required pursuant to procurement regulations pertaining to **contracts/purchases with information technology as a component of the scope of service/product specifications**. This request seeks to ensure that ITSD is aware of and has an opportunity to review the procurement detailed below and in the attached document(s). **This requirement applies to any procurement method regardless of dollar amount.** ITSD Contract Services will review, comment, and return to the Division Submitter no later than ten (10) business days from the date submitted.

**Is this a Fee-for-Service Contract?** Yes

**Is this a Grant Contract?** Yes

**Is this a one-time purchase?** Yes

**Is this a subscription purchase?** Yes

**Division/Program Name:** Division of Laboratory Services

**Contact name and phone number/email address:** Kevin Woods / 615-262-6320 / Kevin.Woods@tn.gov

**Description of procurement and business need.**

Multi-year contract for a reagent rental agreement with Luminex Corp. This contract is used for testing CFDNA in the Newborn Screening section. The rental instruments require connection to the State network for the use of shared drives. It does not require the need for connection to the domain.

**Applicable RFS or Purchase Requisition #: Requisition # 0000186558****Attachments Supporting Request** (mark all applicable)

Note: The complete draft procurement document and the applicable documents listed below must accompany this request when submitted to ITSD. Special Contract Requests and Amendment Requests without Agency Head signature are acceptable. ITSD is aware that these documents will not have CPO signature when submitted with this request.

**Relevant Attachments for Service Procurement**

Attached

- Solicitation Document
- Special Contract Request
- Amendment Request
- Proposed Contract/Grant or Amendment
- Original Contract/Grant and Previous Amendments (if any)

**Relevant Attachments for Goods Procurement**

Attached

- Product Specifications
- Narrative Purchase Justification including Information Technology Impacted

*ITSD USE ONLY***Information Systems Plan (ISP) Project Applicability**

To avoid delay of OIR pre-approval, the applicability of an ISP project to the procurement must be confirmed with agency IT staff prior to submitting this request to OIR. If questions surround whether an ISP is not applicable, Agency IT Contact should contact OIR Planning with questions concerning the need for an ISP project.

- Applicable – Approved ISP Project#

**Agency ITSD Contact's Summary of the Information Technology Services Involved**

Clearly identify included technologies such as system development/maintenance, security, networking, etc. As applicable, identify the contract or solicitation sections related to the IT services.



## E-Health Pre-Approval Endorsement Request E-Mail Transmittal

**TO :** Office of e-Health Initiatives  
Department of Finance & Administration  
E-mail: [office.eHealth@tn.gov](mailto:office.eHealth@tn.gov)

**FROM :** Scott Creel, TDH - ITSD  
E-mail: [Scott.Creel@tn.gov](mailto:Scott.Creel@tn.gov)

**DATE :** April 03, 2019

**RE :** Request for eHealth Pre-Approval Endorsement

<b>Applicable RFS #</b>	<b>HL00000288</b>
<b>Office of e-Health Initiatives Endorsement Signature &amp; Date:</b>	
 4/4/2019	
<b>Office of e-Health Initiatives</b>	

Office of e-Health Initiatives (eHealth) pre-approval endorsement is required pursuant to procurement regulations pertaining to contracts with medical/mental health-related professional, pharmaceutical, laboratory, or imaging type services as a component of the scope of service. This request seeks to ensure that eHealth is aware of and has an opportunity to review the procurement detailed below and in the attached document(s). This requirement applies to any procurement method regardless of dollar amount.

Please indicate eHealth endorsement of the described procurement (with the appropriate signature above), and return this document via e-mail at your earliest convenience.

<b>Contracting Agency</b>	<b>Health</b>
<b>Agency Contact</b> (name, phone, e-mail)	<b>Scott Creel, (615) 770-1152, <a href="mailto:Scott.Creel@tn.gov">Scott.Creel@tn.gov</a></b>
<b>Attachments Supporting Request</b> (as applicable – copies without signatures acceptable)	
Solicitation Document Special Contract Request Amendment Request Proposed contract or amendment	
<b>Subject Medical/Mental Health-Related Service Description</b> (Brief summary of eHealth services involved. As applicable, identify the contract and solicitation sections related to eHealth services.)	
Lab Instrumentation Renewal	



## STS Pre-Approval Endorsement Request E-Mail Transmittal

**TO :** STS Contracts  
Department of Finance & Administration  
E-mail : [it.abc@tn.gov](mailto:it.abc@tn.gov)

**FROM :** Scott Creel, TDH - ITSD  
E-mail : [Scott.Creel@tn.gov](mailto:Scott.Creel@tn.gov)

**DATE :** April 3, 2019 Received by STS on Wednesday, April 3, 2019

**RE :** Request for STS Pre-Approval Endorsement

**Applicable RFS # HL00000288**

**State Security Confidential Information Applicability**

Under Tenn. Code Ann. §10-7-504(i) vendor identity or a description of the goods or services provided by the vendor shall be confidential.

- Applicable  
 Not Applicable

Additional language is attached and endorsement is contingent upon inclusion of this additional language:

- Applicable  
 Not Applicable

**STS Endorsement Signature & Date:**

**Stephanie Dedmon,  
CIO (WMH)**

Digitally signed by Stephanie  
Dedmon, CIO (WMH)

Date: 2019.04.12 17:16:45 -05'00'

**Chief Information Officer**

*NOTE: Proposed contract/grant support is applicable to the subject IT service technical merit.*

Strategic Technology Solutions (STS) pre-approval endorsement is required pursuant to procurement regulations pertaining to contracts with information technology as a component of the scope of service. This request seeks to ensure that STS is aware of and has an opportunity to review the procurement detailed below and in the attached document(s). This requirement applies to any procurement method regardless of dollar amount.

Please indicate STS endorsement of the described procurement (with the appropriate signature above), and return this document via e-mail at your earliest convenience.

**Contracting Agency**

**Health**

<b>Applicable RFS #</b> HL00000288	
<b>Agency Contact</b> (name, phone, e-mail)	<b>Scott Creel, (615) 491-0612 Scott.Creel@tn.gov</b>
<p><b>Attachments Supporting Request</b> (mark all applicable)</p> <p>Note: The complete draft procurement document and the applicable documents listed below must accompany this request when submitted to STS. Special Contract Requests and Amendment Requests without Agency Head signature are acceptable. STS is aware that these documents will not have CPO signature when submitted with this request.</p> <p> <input type="checkbox"/> Solicitation Document  <input checked="" type="checkbox"/> Special Contract Request  <input type="checkbox"/> Amendment Request  <input type="checkbox"/> Proposed Contract/Grant or Amendment  <input type="checkbox"/> Original Contract/Grant and Previous Amendments (if any) </p>	
<p><b>Information Systems Plan (ISP) Project Applicability</b></p> <p>To avoid delay of STS pre-approval, the applicability of an ISP project to the procurement must be confirmed with agency IT staff prior to submitting this request to STS. If necessary, agency IT staff should contact STS Planning with questions concerning the need for an ISP project.</p> <p>IT Director/Staff Name Confirming (required): Mike Newman, Health CIO</p> <p> <input type="checkbox"/> Applicable – Approved ISP Project#  <input checked="" type="checkbox"/> Not Applicable </p>	
<p><b>Subject Information Technology Service Description</b></p> <p>Provide a brief summary of the information technology services involved. Clearly identify included technologies such as system development/maintenance, security, networking, <i>etc.</i> As applicable, identify the contract or solicitation sections related to the IT services.</p> <p>Lab instrumentation support/maintenance renewal</p>	

March 21, 2019

Attn: THOMAS CHILDS  
TENNESSEE DEPARTMENT OF HEALTH  
630 HART LN  
LABORATORY SVCS  
NASHVILLE, Tennessee 37216

**Re: Luminex as the Sole Source Provider**

This letter is to certify that Luminex Corporation is the sole manufacturer of the following products (for purposes of this letter, collectively referred to as "Luminex Products"):

Catalog No.	Product Description
I027C0231	xTAG Cystic Fibrosis (CFTR) 39 kit v2 - US IVD

These Luminex Products can only be run on Luminex System(s). The Luminex Products set forth above, may only be purchased through Luminex Corporation and no other entity is authorized to sell or distribute the Luminex Product(s) to the Center for Disease Control, Public Health Laboratories, or other U.S. government affiliated laboratories within the United States.

Luminex Corporation provides this letter as the Sole Source for the Luminex Product(s) set forth herein to exempt purchases of such from competitive bidding since they may only be purchased through Luminex Corporation.

Should you have any questions please don't hesitate to contact Luminex at 512-219-8020.

Best regards,



Reid Sadler  
VP Sales & Marketing Americas  
Luminex Corporation

QUOTATION INFORMATION for: TENNESSEE DEPARTMENT OF HEALTH	BILL TO CONTACT	PRIMARY CONTACT INFORMATION
<b>Created Date:</b> 3/14/2019 <b>Quotation Number:</b> Q-00011560 <b>Length of Agreement:</b> 36 months <b>Expiration Date:</b> 6/12/2019 <b>Reference Number:</b> 49680	THOMAS CHILDS 630 HART LN NASHVILLE, Tennessee 37216 United States	<b>THOMAS CHILDS</b> Public Health Educator (615) 262-6446  thomas.childs@tn.gov
LUMINEX BUSINESS MANAGER	SHIP TO CONTACT	CUSTOMER LOCATION
Rebecca Edmondson  redmondson@luminexcorp.com	THOMAS CHILDS 630 HART LN NASHVILLE, Tennessee 37216 United States	630 HART LN NBS 5TH FL NASHVILLE, TN, 37216 United States

## REAGENT RENTAL

## INSTRUMENTATION AND MAINTENANCE/SUPPORT PACKAGES

PART NO.	QTY	DESCRIPTION	PRICE/UNIT (USD)	EXTENDED PRICE (USD)
LX200-XPON3.1	1	Luminex 200 System with xPONENT 3.1	25,000.00	Included
SLA-LX200-PLAT-RR	2	LX200 Platinum RR Maintenance and Support Package	8,472.00	Included

## xTAG/NxTAG KITS

PART NO.	ANNUAL MINIMUM QUANTITY	DESCRIPTION	ANNUAL TEST VOLUME	PRICE/TEST (USD)	PRICE/UNIT (USD)	ANNUAL MINIMUM PURCHASE (USD)
I027C0231	53	xTAG Cystic Fibrosis (CFTR) 39 kit v2 - US IVD	5,000	31.00	2,976.00	157,728.00

## TOTALS SUMMARY

		<b>TOTAL ANNUAL PRICE (USD)</b>	<b>157,728.00</b>
		<b>Shipping &amp; Handling (USD)</b>	<b>0.00</b>
		<b>Sales Tax Amount (USD)</b>	<b>0.00</b>
		<b>GRAND TOTAL (USD)</b>	<b>157,728.00</b>

To facilitate processing your order, please provide this Quotation number (Q-00011560) when submitting a purchase order to [orders@luminexcorp.com](mailto:orders@luminexcorp.com)

Payment terms are NET 30  
FOB Luminex's shipping point

**All prices quoted are in: USD**

Prices are subject to federal and local taxes as applicable.

Maintenance and Support coverage will only be initiated after fully executed Luminex Maintenance and Support Agreement is in place.

The pricing on this Quotation will expire on 6/12/2019

Luminex's Standard Terms and Conditions of Sale are incorporated by reference into this Quotation and any resulting contract. By issuing a purchase order or otherwise ordering or accepting products or services, you expressly confirm that you intend to be bound by and agree to the terms of this Quotation and Luminex's Standard Terms and Conditions of Sale to the exclusion of all other terms not expressly agreed to in writing by an authorized representative of Luminex. Luminex's Standard Terms and Conditions of Sale can be found at <https://www.luminexcorp.com/resource/legal-information/terms-conditions-of-sale/>

### Minimum Specifications for CF DNA Mutation Analysis Reagent Rental Contract

1. Kit must be FDA cleared for blood and able to be validated for 1/8 inch dried blood spots.
2. Reagents and equipment shall be used for the simultaneous detection and identification of genetic mutations and variations of the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene to establish CF carrier status or establish CF diagnosis.
3. Assay workflow must be in the following order: DNA extraction and purification, multiplex PCR reaction to amplify purified DNA, allele specific primer extension in which primers bind to target DNA fragments if present with incorporation of a reporter label, bead hybridization in which colored beads with anti-TAG sequences bind to complementary targeted sequences, and lastly identification of bead color and presence or absence of labeled target by software with results identified as wild type or heterozygous or mutant alleles.
4. Must at least test for the following mutations if not more:

delF508	A455E	R1162X	delI507	1717-1G>A	3659delC	G542X
R560T	3849+10kbC>T	G85E	R553X	W1282X	R117H	G551D
N1303K	621+1G>T	1898+1G>A	5/7/9T	711+1G>T	2184delA	F508C
R334W	2789+5G>A	I507V	R347P	3120+1G>A	I506V	1078delT
394delTT	Y122X	R347H	V520F	A559T	S549N	S549R
1898+5G>T	2183AA>G	2307insA	Y1092X	M1101K	S1255X	3876delA
3905insT						

5. If test is positive for R117H mutation, software will automatically display results for these variants: IVS8-5T, IVS8-7T, IVS8-9T.
6. If test is positive for delta F508 or deltaI507 mutation then F508C is assessed for interpretation.
7. Uses 2183AA>G mutation to evaluate 2184delA mutation.
8. Must provide 53 each of the following reagents and supplies or equivalent annually: xTAG CFTR PCR Primer mix v2 (includes dNTPs), xTAG CFTR ASPE Primer Mix A v2 (includes dNTPs), Platinum Tfi Exo(-) DNA Polymerase (5 units/ $\mu$ L), Platinum Tfi Reaction Buffer 5x, Tfi 50mM MgCL<sub>2</sub>, xTAG Exonuclease I (10  $\mu$ L), xTAG Shrimp Alkaline Phosphatase (SAP) (1 unit/ $\mu$ L), xTAG CFTR Bead Mix A v2, xTAG 10X Reporter Buffer, xTAG SAPE (1mg/mL).
9. Vendor must provide the following equipment or equivalent to enable performance of test as part of the reagent rental:

Quantity	Equipment
1	Luminex 200 System with xPONENT 3.1

1	Thermal cycler
3	LX200 platinum reagent rental maintenance and support package

10. The test method must produce results for reporting no more than 5.5 hours after start of procedure.
11. Procedure must have stopping points within the processing allowing for overnight storage and resumption of testing the following day.
12. Procedure must be able to be performed on the bench top or within dead air boxes without requiring a clean room setup.
13. Must have capability of testing extracts of input DNA concentrations between 10 ng/ $\mu$ L to 1.5  $\mu$ g/mL but optimally at 50 ng/ $\mu$ L.
14. Must be compatible with Qiagen DNA extraction protocol for dried blood spots.
15. Vendor is the manufacturer of the reagent kits.
16. Vendor shall supply an updated operator's manual for any instrumentation provided.
17. The vendor shall be responsible for maintenance of all leased equipment and provide at least 3 preventive maintenance visit per year. Equipment shall be maintained according to the original manufacturer's maintenance standard. Equipment shall remain state of the art.
18. Vendor will furnish software for analyzing results. Vendor will also provide reporting software user manual, CD rom of reporting software and any upgrades for the lease life.
19. Vendor will furnish technical support from 8:00 a.m. to 4:30 p.m. cst seven days a week excluding holidays. Vendor shall provide a toll free number. Equipment shall be repaired within one week or vendor will provide new equipment. Vendor must supply temporary equipment for use while repairs are being made so that testing and workflow remains uninterrupted.
20. Vendor shall provide training on-site at no cost to State of Tennessee for at least 2 days on the method for two people or more.