TEXAS
Health and Human Services

Cecile E. Young, Executive Commissioner

Request for Proposals (RFP)
for
Newborn Screening Cystic Fibrosis DNA Testing System
RFP No. HHS0009891
Date of Release: April 30, 2021

Responses Due: June 1, 2021 by 10:30 a.m. Central Time

NIGP Class/Item Codes

193-36	Diagnostic Reagents and Supplies, Automated Chemistry;
193-89	Test Kits and Supplies, Chemistry (Not Otherwise Classified);
490-43	Laboratory and Scientific Equipment and Supplies (Not Otherwise Classified);
938-63	Laboratory Equipment and Accessories: Specialized, Biochemistry, Biology, Chemistry, etc, Maintenance and Repair; and
979-53	Laboratory Equipment and Accessories, Rental or Lease: Biochemistry, Biology, Environmental Science, etc.

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ARTICLE I. EXECUTIVE SUMMARY, DEFINITIONS, AND AUTHORITY

1.1 EXECUTIVE SUMMARY

The State of Texas, by and through the Texas Health and Human Services Commission (**HHSC**) and the Department of State Health Services (**DSHS** or **System Agency**), seek to enter into one contract with a single Respondent to provide a Newborn Screening (**NBS**) Cystic Fibrosis DNA Testing System. This NBS Testing System will perform neonatal screening for the detection and identification of genetic mutations and variations of the Cystic Fibrosis Transmembrane Conductance Regulator (**CFTR**) gene for specimens collected on babies born in Texas in accordance with the specifications contained in this Request for Proposal (**RFP**).

To be considered for award, Respondents shall execute **Exhibit A**, **HHS Solicitation Affirmations, v 1.7**, and **Exhibit F, HUB Subcontracting Plan** of this Solicitation and provide all other required information and documentation as set forth in this Solicitation.

Information regarding DSHS and its programs is available online and can currently be accessed at http://www.dshs.texas.gov/.

1.2 DEFINITIONS

Refer to **Exhibit B, HHS Uniform Terms and Conditions – Vendor, v 3.2**, for additional definitions.

Additionally, as used in this Solicitation, unless the context clearly indicates otherwise, the following terms and conditions have the meanings assigned below:

"Addendum" means a written clarification or revision to this Solicitation issued by HHS.

"Award Consideration (AC) Documents" means documents that must be submitted with the Solicitation Response to be considered for negotiations or award but may be remedied by the Respondent at the option of HHS.

"Business day" means for this solicitation Monday-Saturday, excluding State holidays.

"CFTR" means the Cystic Fibrosis Transmembrane Conductance Regulator gene. The Test System is used to detect and identify this gene's mutations in newborn screenings.

"Equipment" means, per a reagent rental, all required equipment associated with the reagent kits and testing method to be provided at no additional cost to the System Agency.

"ESBD" means the Electronic State Business Daily, the electronic marketplace where State of Texas bid opportunities over $25,000 are posted. The ESBD may currently be accessed at http://www.txsmartbuy.com/esbd.

"Final Written Solicitation Response Scores" refers to the final scoring of the written response as documented in the Solicitation. The written response score may be adjusted by Interviews or outlier meetings as advertised in the Solicitation, resulting in the Final Written Response Score.

"Health and Human Services" or "HHS" has the same meaning as the definition in **Exhibit B, HHS Uniform Terms and Conditions – Vendor, v 3.2**.

"Health and Human Services Commission" or "HHSC" has the same meaning as the definition in **Exhibit B, HHS Uniform Terms and Conditions – Vendor, v 3.2**.

"HUB" has the same meaning as the definition in **Exhibit B, HHS Uniform Terms and Conditions – Vendor, v 3.2.**

"HUB Subcontracting Plan" or "HSP" means written documentation regarding the use of subcontractors, which is required to be submitted with all responses to state agency contracts with an expected value of $100,000 or more where subcontracting opportunities have been determined by the state agency to be probable. The HSP subsequently becomes a provision of the awarded Contract and shall be monitored for compliance by the state agency during the term of the Contract.

"LIMS" means the Laboratory Information Management System which is part of the DSHS existing software-based solution.

"Respondent" means the entity responding to this Solicitation.

"Solicitation" means this RFP including exhibits and Addenda, if any.

"Solicitation Consideration (SC) Documents" means documents that must be submitted with the Solicitation Response in order to be considered for evaluation and cannot be resubmitted or have errors remedied after the submission due date and time in **Section 3.1, Schedule of Events** has passed.

"State" means the State of Texas and its instrumentalities, including HHSC, the System Agency, and any other state agency, its officers, employees, or authorized agents.

"System Agency" means DSHS for this solicitation and has the same meaning as the definition in **Exhibit B, HHS Uniform Terms and Conditions – Vendor, v 3.2**.

"Testing System" means the reagents, consumables, associated software and workstations, and Equipment, including test method validation/verification, test method evaluation and training, and test method technical troubleshooting required to obtain test results for neonatal screening of CTFR mutations.

1.3 AUTHORITY

The System Agency is soliciting the services listed herein under Tex. Gov't Code §2155.144 and Tex. Health and Safety Code §12.051.

ARTICLE II. SCOPE OF WORK/SPECIFICATIONS

2.1 DESCRIPTION OF SERVICES

2.1.1 Services and Contractor Requirements

Contractor shall provide a NBS Cystic Fibrosis (CF) deoxyribonucleic acid (DNA) Testing System to perform neonatal screening for the detection and identification of genetic mutations and variations of the CFTR gene. The Testing System must meet all specifications below:

A. Contractor shall provide all reagents, consumables, associated software and workstations, and Equipment, including test method validation/verification, test method evaluation and training, and test method technical troubleshooting at no additional cost.

B. Contractor shall provide an **estimated annual quantity** of 7,000 reagent kits. DSHS reserves the right to increase/decrease quantities depending upon needs and at times and quantities that DSHS will set.

C. Contractor shall provide **reagent kits with the following specifications**:

1. The test method must utilize DNA extracted from a 1/8" disk punched from dried blood spotted on Whatman #903 filter paper or equivalent.

2. The test method must be compatible with an alkaline lysis, QuantaBio Extracta DBS (Part# 95171-500), or Qiagen DNA (Part# 159992 and 159994) extraction protocol for dried blood spots.

3. The test method must have a repeat rate of less than 10% as determined by DSHS Laboratory staff.

4. The test method must be able to run from the beginning of nucleic acid extraction to the release of final results for a daily batch of approximately 32 specimens within eight working hours.

5. The reagent kit must identify, at minimum, the CFTR mutations listed in **Table 1- CFTR Mutations to Be Identified** below. If the Respondent offers more than one type of reagent kit that meet the minimum requirement for the mutation panel, separate additional pricing in **Form D, Cost Proposal** can be submitted for each kit.

Table 1 - CFTR Mutations to Be Identified

Mutations					
1)	deltaF508	2)	R117H	3)	D1152H
4)	G542X	5)	3120+1G>A	6)	G551D
7)	3849+10kbC>T	8)	S549N	9)	N1303K
10)	3876delA	11)	621+1G>T	12)	R553X
13)	deltaI507	14)	1717-1G>A	15)	2789+5G>A
16)	R1162X	17)	L206W	18)	R347H
19)	Q493X	20)	R334W	21)	3659delC
22)	1078delT	23)	G85E	24)	Y1092X
25)	R347P	26)	W1282X	27)	2307insA
28)	711+1G>T	29)	A455E	30)	1898+1G>A
31)	2183AA>G	32)	3905insT	33)	S549R
34)	935delA	35)	2055del9>A	36)	394delTT
37)	E60X	38)	V520F	39)	2184delA
40)	406-1G>A	41)	S1196X	42)	W1089X
43)	R560T	44)	3199del6	45)	A559T
46)	M1101K	47)	R75X	48)	G330X
49)	R1158X	50)	3791delC	51)	S1255X
52)	CFTR dele2,3	53)	Q890X	54)	2143delT
55)	R1066C	56)	2184insA	57)	2988+1GA
58)	3272-26A->G	59)	621+1G->T	60)	c.2657+2_2657+3insA
61)	c.579+3A>G	62)	D1270N	63)	G576A
64)	I148T	65)	M470V	66)	P67L
67)	R117C	68)	R352Q	69)	R668C
70)	S466X	71)	S945L	72)	V232D

6. Reagent kit must provide automatic reflex testing for R117H positive results for the intron 8 mutations known as IVS8-5T/7T/9T.

D. For any **changes in the quality of reagent**, and consumable supplies, such as conditions which may affect test method or Equipment performance:

1. Contractor shall be notified by DSHS by telephone or email when an issue with the quality of reagents is identified;

2. Contractor shall provide technical telephone assistance 8:00am – 5:00pm CST, Monday through Saturday;

3. Contractor shall provide valid products within 14 calendar days to assure testing continuity;

4. Contractor shall provide, at no charge, replacement kits or consumable supplies for those identified as unusable; and

5. Contractor shall provide written notification to DSHS point of contact (to be provided upon the execution of the Contract) a maximum of 10 calendar days after Contractor's knowledge of any changes to the reagent kits or to the package inserts. Contractor shall also provide written notice of the change to the reagent kit(s) or package inserts with the delivery of the reagent kit. Such notification must be visually easy to identify or locate.

E. Contractor shall **deliver reagent kits** according to the following specifications:

1. Reagent kit must have latest expiration possible and at minimum 6 months expiration upon receipt by DSHS;

2. Reagent kits must be shipped only upon request from DSHS, approximately every 3-4 months;

3. Reagents kits must be supplied as a single lot in each shipment. Contractor shall provide written confirmation of the lot size upon request and allow DSHS the ability to request a single lot. A new lot of reagent kits must be provided at least 30 calendar days in advance of usage to allow for DSHS in-house quality control assessment;

4. Reagent kits must be shipped no more than 3 Business days after Contractor's receipt of order from DSHS, at Contractor's expense;

5. Shipping method for temperature-sensitive testing reagents must prevent damage by environmental conditions such as heat or cold. Delivery to DSHS must be coordinated with DSHS;

6. Delivery of temperature-sensitive testing reagents must not occur over a weekend or State holiday; and

7. Temperature-sensitive testing reagents must be packaged and shipped in a way that must maintain the integrity of the reagents, and according to the manufacture's specifications for the products.

F. Contractor shall provide **Equipment** according to the following:

1. All Equipment required to perform dried blood spot specimen preparation and DNA extraction (if required or recommended by the kit manufacturer's package insert) shall be supplied by the Contractor as part of the reagent rental at no additional cost. However, reagents necessary for DNA extraction do not have to be provided by the Contractor and may be purchased separately by DSHS;

2. All Equipment and/or reagents needed for DNA quantification (if required or recommended by the kit manufacturer's package insert) shall be provided by the Contractor at no additional cost;

3. All Equipment required for testing shall be supplied by the Contractor at no additional cost;

4. Equipment must provide barcode identification to identify test method and specimen group for all specimens being processed;

5. Equipment must have sufficient power back-up such as uninterruptible power supply (UPS) with a minimum capacity of 15 minutes coverage to provide protection during power surges and/or during the switch from regular to emergency power during a power failure;

6. Quantity of Equipment must be sufficient for DSHS staff to reasonably process the expected workload in an 8-hour workday, provide redundancy for Equipment maintenance downtime and be acceptable to DSHS;

7. All Equipment required for testing must fit within DSHS defined location/space available; and

8. Contractor shall provide required Equipment upgrades at least 30 calendar days prior to termination of Equipment's industry life cycle, as approved by DSHS to maintain optimum Equipment functionality at no additional cost.

G. Contractor shall provide maintenance and technical support to include each of the following:

1. Contractor shall retain ownership of all Equipment supplied and be responsible for all Services and repairs required for sustained operation during the life of the Contract at Contractor's expense to ensure consistent and accurate operation of the Equipment;

2. Contractor shall provide ongoing analytical technical support for provided reagent kits, consumables, associated software and workstations, and Equipment. Support shall include functionality of Equipment to LIMS interfaces;

3. DSHS shall contact Contractor for any technical support needs. Contractor shall provide 1-hour response time via telephone or email Monday through Saturday 8:00am – 5:00pm CT;

4. Contractor shall provide a toll-free number and telephone technical support 8:00am-5:00pm CT, Monday through Saturday at no additional cost;

5. Contractor shall provide replacement part(s) and/or on-site service, at no additional cost, within 24 hours if Equipment disfunction(s) cannot be resolved via telephone by the end of the work day when the problem has been reported, to allow no more than 48 hours of down time. Contractor shall supply temporary Equipment, at no additional cost, for use while repairs are being made so that testing and workflow remains uninterrupted;

6. Contractor shall supply an updated operator's manual for any Equipment provided during the life of the Contract;

7. Contractor shall be responsible for maintenance of all leased Equipment and provide at minimum one (1) preventative maintenance service visit at DSHS per year at no additional charge to be scheduled by the Contractor with DSHS staff at least 3 calendar days prior to the due date of preventative maintenance. Equipment shall be maintained according to the original manufacturer's maintenance standard. Equipment must remain in good working condition for the life of the Contract; and

8. Contractor shall provide summary reports of any Services performed at time of issue resolution or preventative maintenance service, including a list of work completed and data obtained during parameter checks at no additional cost.

H. Contractor shall provide operation hardware and software to include the following:

1. Contractor shall supply and install all computers as identified within this Solicitation with at least a 20-inch monitor, software, printer, and peripherals needed to operate the Equipment.

2. Contractor shall supply and install, upon DSHS approval, software/hardware and Equipment upgrades, if available, at no extra charge for the life of the Contract;

3. Contractor shall provide desktop computers to enable performance of the test method as part of the reagent rental at no additional cost and include the following:

   a. Computer operating system must be able to interact with all major internet browsers and their various versions. Computer operating system must support the version currently used by DSHS and the version prior. The computer operating system must have at least 4 GB of RAM (physical memory).

   b. Computer must have the ability to be connected to the DSHS network to allow automatic data transfer to a designated folder to allow data merging into the existing LIMS.

   c. The DSHS Laboratory currently uses PerkinElmer Specimen-Gate computerized information system software to process specimens and to maintain accurate sample identification and tracking. Contractor's Equipment must be able to accept a "load list of specimens/plate" from the PerkinElmer Specimen Gate software and provide an export of the test results to the PerkinElmer Specimen Gate software.

   d. Contractor shall provide and maintain a correct bi-directional interface format and solution at no additional cost.

1) An example of the "load list of specimens/plate" is shown in **Table 2** below**:**

Table 2

1.	NEGATIVE
2.	POSITIVE
3.	20151210210#|#908644
4.	20151210675
5.	20151210815
6.	20151465038
7.	20151474038
8.	20151474231
9.	20151474247
10.	20151474385
11.	20151474387
12.	20151474458
13.	20151474604
14.	20151474613
15.	20151474716
16.	NTC

2) The specifications for exporting the results are as follows: At a minimum, the Excel or csv file produced must have the required data needed for Specimen-Gate to associate the results in the system including: Run identifier, run date, sample ID, mutation, and result.

e. Contractor shall allow the computer to be interfaced with the DSHS network and shall allow installation of any necessary software. Contractor shall be responsible for providing the correct interface format and solution at no additional cost.

f. Contractor shall allow all DSHS network security and management configurations required by established DSHS policy to maintain network security and restrict access as necessary.

g. Contractor shall provide license for the latest version of Symantec Endpoint Protection at no additional cost.

h. The computer, monitor, printer, peripherals, and Contractor software must remain under maintenance by Contractor and necessary upgrades, repairs, and/or replacements shall be provided at no extra charge during the Contract period and any renewals.

i. Contractor shall provide a data repository, in case of network downtime, and the capability to transfer data once network connection is restored. DSHS owns all data on any data repository that is created as a part of the Contract.

j. Contractor's software shall be compatible with future critical operating system and security patches and future OS service packs.

4. Contractor shall furnish software for analyzing results and at least five user licensed copies at no additional cost. Contractor shall also provide reporting software user manual, DVD, downloadable installer, or other media as appropriate for reporting software, and any upgrades for the life of the Contract period and any renewals at no additional cost.

I. Contractor shall provide installation, training, and validation requirement as follows:

1. Contractor shall provide building modifications, upon DSHS approval, needed to accommodate Equipment installation at Contractor's expense.

2. Contractor shall deliver and install Equipment within 30 calendar days of Contractor's receipt of the DSHS purchase order, at no additional cost.

3. Contractor shall provide technical training on-site at the DSHS Laboratory to staff members for all tests that will be newly implemented or modified for the life of the Contract and as requested by DSHS, at no additional cost;

4. Contractor shall provide training within 7 calendar days after installation and receipt of testing reagents and consumables and be completed within 3 Business days;

5. Training must cover all applicable technical aspects of tests, methods and equipment including explanation of test method and general troubleshooting steps;

6. Contractor shall provide a training certificate to each DSHS staff that completes the training;

7. Contractor shall provide test method validation to the extent requested by DSHS for each reagent kit provided by the Contractor that will be newly implemented for the life of the Contract. Contractor shall provide reagent kits and consumables for validation at no additional cost. New test method validation typically includes approximately 250 specimens.

8. Validation must be conducted on-site at DSHS Laboratory. Reagents and Equipment must pass validation/verification process conducted at DSHS. The process must include studies to determine the accuracy, precision, sensitivity, specificity, reference range, reportable range, and carryover rate of the test method

to meet the criteria listed in the package insert or specific acceptance criteria defined by DSHS.

9. All reagents and Equipment shall meet DSHS requirements. If the validation is unacceptable, Contractor shall assist DSHS to perform additional testing to meet DSHS defined requirements. If the validation continues to be unacceptable, DSHS shall reject the reagent kit or Equipment, and the Contract may be terminated.

2.1.2 Support/Backup Plan

Respondent shall propose a backup plan for ensuring continuity of the DSHS NBS CF DNA Testing System during emergency situations affecting DSHS or Respondent. The backup plan must include resources available to Respondent to assist DSHS and address Equipment, reagent kits, consumables, and software emergencies.

Respondent shall provide back-up testing services in case of emergencies, including information as to test method, CFTR mutations list, specimen shipping and reporting logistics, turnaround time, daily specimen volume capacity, and cost per specimen.

2.1.3 Transition Plan

A. Upon expiration or termination of the Contract that resulted from this RFP and the selection of a new Contractor, the Contractor shall work under DSHS supervision for a minimum period of 9 months prior to the expiration of the Contract to ensure the orderly transfer and efficient transition from current Contractor to new Contractor, DSHS management, or management by a third party.

B. During the transition period, the Contractor shall:

1. Participate in meetings or conference calls as directed by DSHS to discuss transition issues;
2. Adhere to DSHS transition timelines; and
3. Continue to provide analytical Equipment, reagents, consumables, associated software and workstations, technical support, and Equipment maintenance throughout the transition period until the new Equipment is validated and in normal operation mode.

C. Once the DSHS Laboratory is fully functioning with the new Contractor, the Contractor shall remove their Equipment from the DSHS Laboratory, as directed by DSHS

2.1.4 Failure to Deliver

A. DSHS shall monitor the performance of the Contract issued under this RFP. The Contractor shall provide all Services and Deliverables under the Contract at an acceptable service and quality level to DSHS and/or HHSC and in a manner consistent with acceptable industry standards, customs, and practice.

B. Scope of Work and Contract Deliverables including, but not limited to, reagent kit components, Equipment, replacement kit components, associated software and

workstations must be delivered, installed or replaced within timeframe set forth in the Contract such that the DSHS Laboratory's ability to maintain current testing is not affected. If the Contractor fails to deliver the required Deliverables and the DSHS Laboratory's ability to maintain current testing is affected, DSHS shall require $3,200 per day in liquidated damages for each DSHS Business day for which the components are not delivered.

C. All reagent kits, consumables, testing Equipment, and workstations are subject to inspection and testing by the System Agency. Authorized DSHS personnel shall have access to Contractor's place of business for the purpose of inspecting contracted merchandise. Testing reagents, testing Equipment and workstations shall meet performance criteria listed in **Article II, Scope of Work/Specifications**. If performance criteria are not met and the problems resolution process does not rectify the issue, the Contractor shall replace reagent kits, Equipment, or workstations at no cost to DSHS.

D. Training, technical support, problem resolution, and maintenance services listed in **Article II, Scope of Work/Specifications** will be subject to inspection and testing by DSHS, to the extent practical at all times and places during the term of the Contract. All inspections by DSHS shall be made in such a manner as to not unduly delay the work. If any Services performed hereunder are not in conformity with the requirements of the Contract, DSHS shall have the right to require the Contractor to perform the Services again in conformity with the requirements of the Contract, at no additional increase in the total Contract amount.

In the event the Contractor fails promptly to perform the Services again or to take necessary steps to ensure future performance of the Services in conformity with the requirements of the Contract, DSHS shall have the right to either:

1. Have the Services performed in conformity with the Contract requirements and charge to the Contractor any cost occasioned to the System Agency that is directly related to the performance of such Services; or
2. Terminate the Contract for cause as provided for in **Exhibit B, HHS Uniform Terms and Conditions – Vendor, v 3.2**.

E. All remedies available to DSHS for breach or anticipatory breach of the Contract by the Contactor are cumulative and may be exercised concurrently or separately and the exercise of any one (1) remedy must not be deemed an election of such remedy to the exclusion of other remedies. Liquidated damages, actual damages, cost projections, injunctive relief or performance bonds may also be invoked either separately or combined with any other remedy in accordance with applicable law.

2.2 CONTRACT AWARD, TERM, AND AMOUNT

2.2.1 Contract Award and Execution

The System Agency intends to award one (1) Contract as a result of this Solicitation. Any award is contingent upon approval of the Executive Commissioner or their designee.

If, for any reason, a final Contract cannot be executed with a Respondent selected for award within sixty (60) calendar days of the System Agency's determination to seek to Contract with that Respondent, the System Agency may negotiate a Contract with the next highest scoring Respondent or may withdraw, modify, or partially award this Solicitation.

2.2.2 Contract Term

The System Agency anticipates that the initial duration of any Contract resulting from this Solicitation shall be for a period of two (2) years. System Agency, at its sole discretion, may renew or extend the Contract. However, in no event may the Contract term, including all renewals and extensions, exceed 5 years. Notwithstanding the limitation in the preceding sentence, System Agency, at its sole discretion, also may extend the Contract for not more than one additional option period to address immediate operational or service delivery needs. If the resulting Contract does not include a defined option period, the extension is limited to one year.

2.2.3 Historical Contract Amount

The Contract amount shall be based on the selected Respondent's Best and Final Offer, as negotiated with the System Agency. Between August 1, 2017 and December 31, 2020, the System Agency has spent a total amount of $815,362.56 on a Newborn Screening Cystic Fibrosis DNA Testing System screening approximately 32 specimens a day, 6 days a week.

2.3 DATA USE AGREEMENT

By entering into a Contract, or purchase order with the System Agency as a result of this Solicitation, Respondent agrees to be bound by the terms of **Exhibit D, Data Use Agreement (DUA)** and **Exhibit D-1, Attachment 2 to the DUA, Security and Privacy Inquiry (SPI)**.

2.4 NO GUARANTEE OF VOLUME, USAGE, OR COMPENSATION

The System Agency makes no guarantee of volume, usage, or total compensation to be paid to any Respondent under any awarded Contract, if any, resulting from this Solicitation. Any awarded Contract is subject to appropriations and the continuing availability of funds.

The System Agency reserves the right to cancel, make partial award, or decline to award a Contract under this Solicitation at any time at its sole discretion.

2.5 GOVERNMENTAL ENTITIES

The selected Respondent shall be bound to specific terms and conditions found in **Exhibit B, HHS Uniform Terms and Conditions - Vendor v 3.2** and **Exhibit C, HHS Additional Provisions v 1.0**. However, to the extent Respondent is a governmental entity, responding to this Solicitation in its capacity as a governmental entity, certain terms and conditions may not be applicable. Furthermore, to the extent permitted by law, if a Solicitation response is received from a governmental entity, the System Agency reserves the right to enter into an interagency or interlocal agreement with the governmental entity in lieu of awarding a Contract as a result of this Solicitation.

ARTICLE III. ADMINISTRATIVE INFORMATION

3.1 SCHEDULE OF EVENTS

EVENT	DATE/TIME
Solicitation Release Date	APRIL 30, 2021
Mandatory HSP Training	MAY 10, 2021 at 10:00 a.m. Central Time
Second Mandatory HSP Training	May 12, 2021 at 2:00 p.m. Central Time
Deadline for Submitting Questions	MAY 14, 2021 at 3:00 p.m. Central Time
Deadline for Courtesy Review of HSP (optional)	MAY 17, 2021 at 5:00 p.m. Central Time
Tentative Date Responses to Questions Posted on ESBD	MAY 21, 2021
Deadline for Submission of Solicitation Responses [NOTE: Responses shall be RECEIVED by HHSC by the deadline.]	JUNE 1, 2021 at **10:30 a.m.** Central Time
Anticipated Notice of Award	AUGUST 2021
Anticipated Contract Start Date	SEPTEMBER 2021

Note: These dates are a tentative schedule of events. HHS reserves the right to modify these dates at any time upon notice posted to the ESBD. Any dates listed after the Solicitation Response deadline shall occur at the discretion of HHS and may occur earlier or later than scheduled without notification on the ESBD.

3.2 CHANGES, AMENDMENT, OR MODIFICATION TO SOLICITATION

HHS reserves the right to change, amend, or modify any provision of this Solicitation, or to withdraw this Solicitation at any time prior to award if it is in the best interest of HHS. Any such revisions shall be posted on the ESBD. It is the responsibility of Respondent to periodically check the ESBD to ensure full compliance with the requirements of this Solicitation.

3.3 IRREGULARITIES

Any irregularities or lack of clarity in this Solicitation should be brought to the attention of the Sole Point of Contact listed in **Section 3.5.1** as soon as possible so corrective Addenda may be furnished to prospective Respondents.

3.4 INFORMALITIES

HHS reserves the right to waive minor informalities in a Solicitation Response if it is in the best interest of HHS. A "minor informality" is an omission or error that, in HHS's determination if waived or modified when evaluating Solicitation Responses, would not give a Respondent an unfair advantage over other Respondents or result in a material change in the Solicitation Response or Solicitation requirements.

3.5 INQUIRIES

3.5.1 Sole Point of Contact

All requests, questions, or other communication about this Solicitation shall be made in writing to HHS's Purchasing Department, addressed to the person listed below (Sole Point of Contact). All communications between Respondents and other System Agency staff members concerning the Solicitation are strictly prohibited. **Failure to comply with these requirements may result in disqualification of Respondent's Solicitation Response.**

Name:	Monique Allen, CTCD, CTCM
Title:	Complex Contract Specialist IV
Email:	monique.allen@hhs.texas.gov

See also, **Section 3.5.3, Exception to Sole Point of Contact** below.

3.5.2 Prohibited Communication

On issuance of this Solicitation, except for the written inquiries described in **Sections 3.5.4, Questions** and **3.5.5, Clarification** below, the System Agency, its representative(s), or partners will not answer any questions or otherwise discuss the contents of this Solicitation with any potential Respondent or their representative(s). Attempts to ask questions by phone or in person will not be allowed or recognized as valid. Respondent shall rely only on written statements issued by or through HHS's designated staff as provided by this section. This restriction does not preclude discussions between affected parties for the purposes of conducting business unrelated to this Solicitation. **Failure to comply with these requirements may result in disqualification of Respondent's Solicitation Response.**

3.5.3 Exception to Sole Point of Contact

The only exceptions to the Sole Point of Contact are the HUB coordinator, or, if expressly directed by the Sole Point of Contact, another designated HHS representative, e.g., during Contract negotiations, if any. Should Respondents have questions regarding proper completion of the HUB Subcontracting Plan, the HUB coordinator may be contacted at Ann.Tillman@hhs.texas.gov.

3.5.4 Questions

HHS will allow written questions and requests for clarification of this Solicitation. Questions must be submitted in writing and sent by email to the Sole Point of Contact listed in **Section 3.5.1** above. Respondents' names will be removed from questions in any

responses released. Questions shall be submitted in the following format. Submissions that deviate from this format may not be accepted:

A. Identifying Solicitation number;

B. Section number;

C. Paragraph number;

D. Page number;

E. Text of passage being questioned; and

F. Question.

Note: Questions or other written requests for clarification must be received by the Sole Point of Contact by the deadline set forth in Section 3.1, Schedule of Events. Please provide company name, address, phone number, fax number, e-mail address, and name of contact person when submitting questions.

3.5.5 Clarification

Respondents shall notify the Sole Point of Contact of any ambiguity, conflict, discrepancy, exclusionary specifications, omission, or other error in the Solicitation in the manner and by the deadline for submitting questions. If a Respondent fails to properly and timely notify the Sole Point of Contact of such issues, the Respondent submits its Solicitation at its own risk, and if awarded a Contract: (1) shall have waived any claim of error or ambiguity in the Solicitation and any resulting Contract, (2) shall not contest the interpretation by any System Agency of such provision(s), and (3) shall not be entitled to additional compensation, relief, or time by reason of ambiguity, error, or later correction.

3.5.6 Responses

Responses to questions or other written requests for clarification will be posted on the ESBD. HHS reserves the right to amend answers prior to the deadline for submission of Solicitation Responses. Amended answers will be posted on the ESBD. It is Respondent's responsibility to check the ESBD. HHS also reserves the right to provide a single consolidated response to all similar questions in any manner at the sole discretion of HHS.

3.5.7 Mandatory HSP Training

HHSC will conduct two HSP Trainings, attendance of which only one is mandatory, at the dates and times listed in **Section 3.1, Schedule of Events.**

People with disabilities who wish to attend the meeting and require auxiliary aids or services should contact the Sole Point of Contact identified in this Solicitation ***at least seventy-two (72) hours before the meeting*** *so appropriate arrangements can be made.*

Participants must register for the webinar conference prior to the event. After registration, participants will receive an e-mail with the actual link to the webinar.

First scheduled HSP Training:

Register here: https://attendee.gotowebinar.com/register/9203425110601147916

Webinar ID: 698-326-339

Second scheduled HSP Training:

Register here: https://attendee.gotowebinar.com/register/7861073146661148432

Webinar ID: 540-453-315

3.5.8 HSP Courtesy Review

A courtesy review of a Respondent's completed HSP is optional and is available upon request to assist in providing a compliant and responsive HSP. This courtesy review may only identify possible deficiencies, but a final compliant determination cannot be provided until the proposal is submitted.

To request a courtesy review, submit the completed HSP including all supporting documentation in a portable document format (PDF) format by e-mail to the HHSC HUB Program Office by or before the Courtesy Review of HSP deadline in the Schedule of Events, Section 3.1.

E-Mail for Courtesy Review: ann.tillman@hhsc.texas.gov
E-mail Subject Line: HSP Courtesy Review, RFP No., and Due Date

HSPs received after the Courtesy Review deadline in **Section 3.1, Schedule of Events**, may not be processed.

The final HSP must be submitted with the Solicitation Response by the deadline in the Schedule of Events. Solicitation Responses that DO NOT include a completed HUB subcontracting plan shall be rejected due to material failure to comply with Texas Government Code Section 2161.252(b). Should Respondents have questions regarding proper completion of the HSP, the HUB coordinator may be contacted at Ann.Tillman@hhs.texas.gov with a copy to the purchaser listed above in **Section 3.5.1, Point-of-Contact.**

3.6 SOLICITATION RESPONSE COMPOSITION

3.6.1 Generally

Failure to submit all Solicitation Consideration and Award Consideration Documents in required format(s) may result in disqualification of the Solicitation Response without further consideration per **Article IX, Submission Checklist**. A Respondent shall prepare a Solicitation Response that clearly and concisely represents its qualifications and capabilities under this Solicitation. Respondent should focus on the instructions and requirements of the Solicitation.

3.6.2 Page Limit and Supporting Documentation

Form A, Narrative Proposal and **Form B, Company Information** of the Solicitation Response should not exceed 60 pages in length, including appendices or attachments, and should be formatted as follows: 8 ½" x 11" paper and 12 pitch font size. If complete

responses cannot be provided without referencing supporting documentation, such documentation must be provided with the Solicitation Response, with specific reference made to the file, page, section, and/or paragraph where the supporting information can be found.

3.6.3 Discrepancies

Discrepancies or disparities between the contents of original Solicitation Responses and copies will be interpreted in favor of HHS or DSHS. If Respondent fails to designate an "ORIGINAL," HHS, in its sole discretion, will determine the version to be used as the original.

3.6.4 Exceptions

Respondents are highly encouraged to seek clarification on any perceived ambiguity relative to the terms and conditions of this Solicitation pursuant to **Section 3.5.4, Questions** prior to submitting exceptions.

Any exception included in a Solicitation Response may result in a Respondent not being awarded a Contract. If a Respondent includes exceptions in its Solicitation Response, Respondent is required to use **Exhibit E, Exceptions Form** and provide all information requested on the form. Any exception that does not provide all required information without qualification in the format set forth in **Exhibit E, Exceptions Form** may be rejected without consideration.

No exception, nor any other term, condition, or provision in a Solicitation Response that differs, varies from, or contradicts this Solicitation shall be considered to be part of any Contract resulting from this Solicitation unless expressly made a part of the Contract in writing by HHS.

3.6.5 Binding Offer

A Solicitation Response should be responsive to the Solicitation as worded, not with any assumption that any or all terms, conditions, or provisions of the Solicitation shall be negotiated. Furthermore, all Solicitation Responses constitute binding offers. **Any Solicitation Response to this Solicitation that includes any type of disclaimer or other statement indicating that the response does not constitute a binding offer may be disqualified.**

3.6.6 Assumptions

Respondent must identify on **Exhibit K, Assumptions Form**, any business, economic, legal, programmatic, or practical assumptions that underlie the Respondent's response to the Solicitation. HHS reserves the right to accept or reject any assumptions. All assumptions not expressly identified and incorporated into any Contract resulting from this RFP are deemed rejected by HHS.

3.7 SOLICITATION RESPONSE SUBMISSION AND DELIVERY

3.7.1 Deadline

Solicitation Responses must be received at the address in **Section 3.7.3, Labeling and Delivery** and be time-stamped by HHSC no later than the date and time specified in **Section 3.1, Schedule of Events**. Solicitation Responses submitted by any method other than those provided by **Section 3.7.2, Submission Options** will **NOT** be considered. **Late submittals will not be accepted.**

3.7.2 Submission Options

A. Submission Option #1: Respondent shall submit the following on two (2) USB drives—one (1) labeled "Original" and one (1) labeled "Copy"— to the address listed in **Section 3.7.3, Labeling and Delivery**:

1. Each USB drive must contain one (1) file named "Original Proposal" that contains the Respondent's entire Proposal in searchable portable document format (PDF).
2. In accordance with **Section 8.1.5, Public Information Act - Respondent Requirement Regarding Disclosure**, each USB drive must contain one (1) file named "Public Information Copy" that contains the Respondent's entire Proposal including all Exhibits and Attachments for this option in searchable PDF, if applicable.
3. Each USB drive must contain one (1) file named "Cost Proposal" that contains the Respondent's Cost Proposal in Excel format with active formulas (compatible with Microsoft Office 2010).
4. In accordance with **Section 6.9, HUB Subcontracting Plan**, each USB drive must contain one (1) file named "HUB Subcontracting Plan" that contains the Respondent's HUB Subcontracting Plan.

B. Submission Option #2: Respondent shall submit the following through the Online Bid Room utilizing the procedures in **Exhibit I, HHS Online Bid Room**:

1. One (1) file named "Original Proposal" that contains the Respondent's entire proposal in searchable PDF.
2. In accordance with **Section 8.1.5, Public Information Act - Respondent Requirement Regarding Disclosure**, one (1) file named "Public Information Copy" that contains the Respondent's entire proposal in searchable PDF, if applicable.
3. One (1) file named "Cost Proposal" that contains the Respondent's Cost Proposal in Excel format with active formulas (compatible with Microsoft Office 2010).
4. In accordance with **Section 6.9, HUB Subcontracting Plan**, one (1) file named "HUB Subcontracting Plan" that contains the Respondent's HUB Subcontracting Plan.

3.7.3 Labeling and Delivery

Respondent must deliver Solicitation Responses by one of the methods below. Solicitation Responses submitted by any other method (e.g., facsimile, telephone, e-mail) will NOT be considered.

U.S. Postal Service	Overnight/Express Mail or Hand Delivery	Online Bid Room
HHSC Procurement and Contracting Services (PCS) Bid Room Attn: Monique Allen P.O. Box 149166 Austin, TX 78714-9166	HHSC Procurement and Contracting Services (PCS) Bid Room Attn: Monique Allen 1100 West 49th Street; Mail Code 2020 Building S Austin, TX 78756	See **Section 3.6.1, Generally** and **Exhibit I, HHS Online Bid Room** **Submit Response Online to, if applicable:** **https://hhs.texas.gov/doing-business-hhs/contracting-hhs/hhs-online-bid-room**

Be Advised, all Solicitation Responses become the property of HHSC after submission and will not be returned to Respondent. It is the Respondent's responsibility to appropriately mark and deliver the Solicitation Response to HHSC by the specified date. A U.S. Postal Service (USPS) postmark or round validation stamp; a mail receipt with the date of mailing, stamped by the USPS; a dated shipping label, invoice of receipt from a commercial carrier; or, any other documentation in lieu of the on-site time stamp WILL NOT be accepted.

Each Respondent is solely responsible for ensuring its Proposal is submitted in accordance with all Solicitation requirements, including, but not limited to, proper labeling of packages, sufficient postage or delivery fees, and ensuring timely receipt by HHSC. **In no event will HHSC be responsible or liable for any delay or error in delivery. Proposals must be RECEIVED by HHSC by the Proposal submission deadline identified in Section 3.1 Schedule of Events, or subsequent Addenda.**

Solicitation Responses submitted via USB by mail or hand delivery shall be placed in a sealed box and clearly labeled as follows:

SOLICITATION NO:	HHS0009891
SOLICITATION NAME	Newborn Screening Cystic Fibrosis DNA Testing System
SOLICITATION RESPONSE DEADLINE	**June 01, 2021 by 10:30 A.M. CST**
PURCHASER NAME:	Monique Allen, CTCD, CTCM
RESPONDENT NAME:	[Respondent Name]

It is Respondent's sole responsibility to ensure that packaging is sufficient to prevent damage to contents. HHSC will not be responsible or liable for any damage and damaged Solicitation Responses will not be considered.

HHS will not be held responsible for any Solicitation Response that is mishandled prior to receipt by HHS. HHS will not be responsible for any technical issues that result in late delivery, inappropriately identified documents, or other submission error that may lead to disqualification (including substantive or administrative) or nonreceipt of the Respondent's proposal.

3.7.4 Alterations, Modifications, and Withdrawals

Prior to the Solicitation Response submission deadline, a Respondent may: (1) withdraw its Solicitation Response by submitting a written request to the Sole Point of Contact identified in **Section 3.5.1**; or (2) modify its Solicitation Response by submitting a written amendment to the Sole Point of Contact identified in **Section 3.5.1**. HHS may request Solicitation Response modifications at any time.

ARTICLE IV. SOLICITATION RESPONSE EVALUATION AND AWARD PROCESS

4.1 EVALUATION CRITERIA

4.1.1 Conformance with State Law

Solicitation Responses shall be evaluated in accordance with Title 10, Subtitle D of the Texas Government Code and specifically Texas Government Code § 2155.144(c)-(d) and 1 Texas Administrative Code Chapter 391, Subchapter B. HHS shall not be obligated to accept the lowest priced Solicitation Response but shall make an award to the Respondent that provides the best value to the State of Texas.

4.1.2 Minimum Qualifications

Respondents must meet the minimum qualifications listed below.

A. Respondents must have recently been in business for a minimum of three (3) years, or the principals/owners shall have had recent ownership/executive management experience in a previous company that provided Services similar to those in **Article II, Scope of Work/Specifications**; Respondent shall provide evidence of years in business on **Form B, Company Information.**

B. Respondents or subcontractor(s) shall have demonstrated experience in providing a Newborn Screening Cystic Fibrosis DNA Testing System. Respondent shall provide evidence of this on **Form B, Company Information.**

C. Respondents must be financially solvent and adequately capitalized as determined based on a review of documentation required by **Section 6.7, Financial Capacity.**

D. Respondents must be authorized to do business in the State of Texas or shall show authorization is currently pending with the Texas Secretary of State located at

https://www.sos.state.tx.us/. Respondent shall provide evidence of their authorization to do business in the State of Texas and/or include an attachment such as a Secretary of State filing.

4.1.3 Selection Methodology

Solicitation Responses that meet the minimum qualifications will be submitted to the evaluation team for review and scoring. Each member of the evaluation team will receive a copy of each responsive Solicitation Response. The evaluators will review the Solicitation Responses considering the criteria list in **Section 4.1.4, Written Response Evaluation Criteria**.

Individual evaluators will score the Solicitation Responses. This procurement will utilize an aggregated individual evaluation methodology as outlined by this section.

The following subsections describe the evaluation process, including any criteria for advancement to the various phases of evaluation if applicable.

4.1.3.1 Initial Compliance Screening

HHS may contact references provided in response to this Solicitation. HHS may contact Respondent's clients or solicit information from any available source. HHS will check the Comptroller's Vendor Performance Tracking System.

HHS assesses all the minimum qualifications prior to starting the evaluation of Solicitation Responses. Screening of minimum qualifications may result in disqualification from evaluation. If, at any time, it is determined by HHS that the Respondent does not meet the minimum qualifications, the Respondent may be disqualified from further consideration.

HHS will disqualify any Solicitation Response that does not include the following completed Solicitation Consideration Documents:

a. **Exhibit A, HHS Solicitation Affirmations v 1.7**;

b. **Exhibit D-1, Attachment 2 to the DUA, Security and Privacy Inquiry (SPI);**

c. **Exhibit F, HUB Subcontracting Plan;**

d. **Form A, Narrative Proposal;**

e. **Form B, Company Information; and**

f. **Form D, Cost Proposal**.

HHSC may disqualify any Solicitation Response that does not include all other Solicitation Consideration Documents, at its sole discretion. See **Article IX, Submission Checklist**.

4.1.3.2 Written Solicitation Response Evaluation

Once each member of the evaluation team has had the opportunity to review the Solicitation Responses, the evaluation team will score the Solicitation Responses against the criteria in **Section 4.1.4, Written Response Evaluation Criteria** and **Exhibit G, Evaluation Tool**.

Solicitation Responses will be evaluated utilizing aggregated individual scoring and any other methods outlined in **Article IV, Solicitation Response Evaluation and Award Process**. The individual evaluator's final scores will be aggregated and averaged, resulting in the Final Written Solicitation Response Scores.

4.1.3.3 Final Award Determination

The final selection for award will be based on the **Section 4.1.3, Selection Methodology** and **Section 4.1.4, Written Response Evaluation Criteria.**

4.1.4 Written Response Evaluation Criteria

Solicitation Responses shall be consistently evaluated and scored in accordance with the following criteria: See also, **Exhibit G, Evaluation Tool**.

A. Capacity to meet specifications in this RFP 40%
B. Compatibility with current DSHS Lab operations 25%
C. Backup Plan 10%
D. Cost 25%

4.2 BEST AND FINAL OFFER

HHSC, on behalf of DSHS, may, at its sole discretion, request BAFOs from all Respondents or only those Respondents whose solicitation responses are ranked most highly by the evaluation committee. The request for a BAFO will allow a Respondent the opportunity to revise its original Solicitation Response, including pricing revisions, if applicable, or leave its Solicitation Response as originally submitted. Revisions must be submitted in the manner and form prescribed by the BAFO request. Requests will be sent to the point of contact provided by the Respondent. HHS is not responsible for a Respondent's failure to timely receive the BAFO request or timely submit its Solicitation Response.

HHSC, on behalf of DSHS, reserves the right to request more than one BAFO from each of the selected Respondents. BAFOs will be evaluated in accordance with the stated criteria in **Section 4.1.4, Written Response Evaluation Criteria** and, if applicable, the final score will be revised. The revised final score, based on Respondent's original Solicitation Response as revised by the BAFO, will determine the ranking of the Respondent(s) following the BAFO request. A request for a BAFO does not guarantee an award or further negotiations.

HHSC, on behalf of DSHS, reserves the right to conduct more than one BAFO. However, a Respondent should provide its best offer in its original Solicitation Response. Respondents should not expect or assume that HHS will request a BAFO.

4.3 QUESTIONS OR REQUESTS FOR CLARIFICATION BY HHS

HHS reserves the right to ask questions or request clarification from any Respondent at any time during the Solicitation process, including during the BAFO process.

ARTICLE V. NARRATIVE PROPOSAL

5.1 NARRATIVE PROPOSAL

5.1.1 Executive Summary

Under **Form A, Narrative Proposal**, Respondent shall provide a high-level overview of the Respondent's approach to meeting the requirements contained in **Article II, Scope of Work/Specifications**. The summary must demonstrate an understanding of the goals and objectives for this Solicitation.

5.1.2 Experience

Under **Form A, Narrative Proposal**, Respondent shall provide a detailed description that demonstrates experience in providing NBS CF DNA Testing System by the Respondent and any proposed subcontractors. Include details regarding experience providing the following: NBS program development and implementation processes and procedures, longevity of the program past Testing System established, problems encountered, and resolutions achieved, and experience and methodology in providing maintenance and support services.

5.1.3 Specifications for the proposed NBS CF DNA Testing System

A. Testing Reagents and Consumables – Under **Form A, Narrative Proposal,** describe the Respondent's ability to provide each of the following:

1. Test method that utilizes DNA extracted from a 1/8" disk punched from dried blood spotted on Whatman #903 filter paper or equivalent;
2. Test method that is compatible with an alkaline lysis, QuantaBio Extracta DBS (Part# 95171-500), or Qiagen DNA (Part# 159992 and 159994) extraction protocol for dried blood spots;
3. Test method that has a repeat rate of less than 10% as determined by DSHS Laboratory staff;
4. Test method that can run from the beginning of nucleic acid extraction to the release of final results for a daily batch of approximately 32 specimens within eight working hours. Provide the time required including the number of required staff;
5. Reagent kit(s) that identifies, at minimum, the mutations listed in **Table 1** of **Section 2.1.1, Services and Contractor Requirements**. If the Respondent offers

more than one type of reagent kit that will meet the minimum requirement for the mutation panel, separate additional pricing in **Form D, Cost Proposal** can be submitted for each kit;

6. Reagent kit must provide automatic reflex testing for R117H positive results for the intron 8 mutations known as IVS8-5T/7T/9T;
7. Provide a list of mutations detectable by the proposed NBS CF DNA Testing System and provide an **internet link** to any published data.**;**

NOTE: Respondent shall not include copies of any published data with the Solicitation Response.

8. Provide a list of all proposed reagents and consumables included in the Response, a description of their use, and quantity required of each. Include the brand name, model number, and quantity for the exact products that are being offered. Reagents shall detect, at minimum, the same mutations listed in **Table 1** of **Section 2.1.1. Service and Contractor Requirements,** of the Solicitation;
9. Provide a list of reagents and supplies that are required for the proposed NBS CF DNA Testing System but are not included in the reagent rental and the estimated cost;
10. Provide an **internet link** to the package insert for each reagent kit of the proposed NBS CF DNA Testing System; and

NOTE: Respondent shall not include copies of any package inserts with the Solicitation Response.

11. Describe shipping methodology for proposed reagent kit(s) including how the reagent kit temperature requirement(s) will be met.

Note: All testing reagents and consumables to be provided by the Respondent must be itemized in Form D, Cost Proposal.

Note: Respondent is required to include on Exhibit F, Exceptions, any differences between what Respondent is proposing to provide and the details listed in Article II, Scope of Work/Specifications of the Solicitation.

B. Testing Equipment - Under **Form A, Narrative Proposal** describe the Respondent's ability to provide each of the following:

1. Equipment required to perform dried blood spot specimen preparation and DNA extraction (if required or recommended by the kit manufacturer's package insert) shall be supplied by the Respondent as part of the reagent rental at no additional cost. However, reagents necessary for DNA extraction do not have to be provided by the Respondent and may be purchased separately by DSHS;

2. Equipment and/or reagents needed for DNA quantification (if required or recommended by the kit manufacturer's package insert) shall be provided by the Respondent at no additional cost;

3. Equipment required for testing shall be supplied by the Respondent at no additional cost;

4. Equipment must provide barcode identification to identify test method and specimen group for all specimens being processed;
5. Equipment with sufficient back-up power such as uninterruptible power supply (UPS) with a minimum capacity of 15 minutes coverage to provide protection during power surges and/or during the switch from regular to emergency power during a power failure;
6. Quantity of Equipment that is sufficient for DSHS staff to reasonably process the expected workload in an 8-hour workday, provide redundancy for Equipment maintenance downtime and be acceptable to DSHS;
7. Equipment required for testing that fits within DSHS defined location and space available. Provide the dimensions of all necessary Equipment;
8. Equipment upgrades at least 30 calendar days prior to termination of Equipment's industry life cycle, as approved by DSHS to maintain optimum Equipment functionality at no additional cost;
9. Provide a list of each piece of Equipment, make and model, a description of the Equipment and their functions, and quantity required;
10. Provide a list of Equipment that are required for the proposed NBS CF DNA testing system but are not be included in the reagent rental and the estimated cost;
11. If Respondent's Equipment has an existing interface with PerkinElmer Specimen Gate software, please specify;
12. If Respondent's Equipment does not have an existing interface, Respondent must describe how the Respondent Equipment will be able to accept a "load list of specimens/plate" from the PerkinElmer Specimen Gate software and provide an export of the test results to the PerkinElmer Specimen Gate software; and
13. Provide an **internet link** to the manufacturer's package insert (instructions), site preparation guide, user's manual, including required routine maintenance procedures, and pipette accuracy and precision specifications, if applicable.

NOTE: Respondent shall not include copies of any manufacturer's user manuals with the Solicitation Response.

C. **Maintenance and Technical Support–** Under **Form A, Narrative Proposal** describe the Respondent's ability to provide each of the following:
1. Retain ownership of all Equipment supplied and be responsible for all Services and repairs required for sustained operation during the life of the Contract at Respondent's expense to ensure consistent and accurate operation of the Equipment;
2. Ongoing analytical technical support for provided reagent kits, consumables, associated software and workstations, and Equipment. Support shall include functionality of Equipment to LIMS interfaces;
3. A 1-hour response time via telephone or email Monday through Saturday 8:00 am – 5:00 pm CT, after receiving DSHS notification of the need for technical support;

4. A toll-free number and telephone technical support 8:00 am-5:00 pm CT, Monday through Saturday and at no additional cost;
5. Replacement part(s) and/or on-site service, at no additional cost, within 24 hours if Equipment disfunction(s) cannot be resolved via telephone by the end of the work day when the problem has been reported, to allow no more than 48 hours of down time. And if needed supply temporary Equipment, at no additional cost, for use while repairs are being made so that testing and workflow remains uninterrupted;
6. Maintenance of all leased Equipment and at minimum one (1) preventative maintenance service visit at DSHS per year at no additional charge to be scheduled by the Contractor with DSHS staff prior to the due date of preventative maintenance. Equipment shall be maintained according to the original manufacturer's maintenance standard. Equipment shall remain in good working condition for the life of the Contract;
7. Summary reports of any Services performed at time of issue resolution or preventative maintenance service, including a list of work completed and data obtained during parameter checks at no additional cost; and
8. Provide an **internet link** to the manufacturer's package insert (instructions), site preparation guide, user's manual including, required routine maintenance procedures, and pipette accuracy and precision specifications, if applicable.

NOTE: Respondent shall not include copies of any manufacturer's package inserts with the Solicitation Response.

D. Hardware and Software – Under **Form A, Narrative Proposal** describe the Respondent's ability to provide each of the following:

1. Supply and install all computers as identified within this Solicitation with at least a 20-inch monitor, software, printer, and peripherals needed to operate the Equipment.
2. Supply and install, upon DSHS approval, software/hardware and Equipment upgrades, if available, at no extra charge during the life of the Contract;
3. Desktop computers to enable performance of the test method as part of the reagent rental at no additional cost and including the following:
   a. Computer operating system that can interact with all major internet browsers and their various versions. Computer operating system must support the version currently used by DSHS and the version prior. The computer operating system must have at least 4 GB of RAM (physical memory);
   b. Computer must have the ability to be connected to the DSHS network to allow automatic data transfer to a designated folder to allow data merging into the existing LIMS;
   c. Computer must have and maintain a correct bi-directional interface format and solution. See **Table 2** in **Section 2.1.1, Services and Contractor Requirements;**

1. The specifications for exporting the results are as follows: at a minimum, the Excel or csv file produced must have the required data needed for Specimen Gate to associate the results in the system including: Run identifier, run date, sample ID, mutation, and result;

d. Computer must be able to interface with the DSHS network and shall allow installation of any necessary software. Respondent shall be responsible for providing the correct interface format and solution at no additional cost;

e. Allow all DSHS network security and management configurations required by established DSHS policy to maintain network security and restrict access as necessary;

f. A license for the latest version of Symantec Endpoint Protection at no additional cost;

g. The computer, monitor, printer, peripherals, and Respondent software must remain under maintenance by Respondent and necessary upgrades, repairs, and/or replacements shall be provided at no extra charge during the Contract period and any renewals;

h. A data repository, in case of network downtime, and the capability to transfer data once network connection is restored; and

i. Respondent software must be compatible with future critical operating system and security patches and future OS service packs.

4. Furnish software for analyzing results and at least five user licensed copies at no additional cost. Respondent shall also provide reporting software user manual, DVD, downloadable installer, or other media as appropriate of reporting software, and any upgrades for the life of the Contract period and any renewals at no additional cost.

E. Installation, Training, and Validation – Under **Form A, Narrative Proposal** describe the Respondent's ability to provide each of the following:

1. Provide building modifications, upon DSHS approval, needed to accommodate Equipment installation at Respondent's expense;

2. Delivery and install Equipment within 30 calendar days of Contractor's receipt of the DSHS purchase order, at no additional cost;

3. Provide technical training on-site at the DSHS Laboratory to staff members for all tests that will be newly implemented or modified for the life of the Contract and as requested by DSHS, at no additional cost;

4. Provide training within 7 calendar days after installation and receipt of testing reagents and consumables and be completed within 3 Business days;

5. Training must cover all applicable technical aspects of tests, methods and equipment including explanation of test method and general troubleshooting steps;

6. A training certificate to each DSHS staff that completes the training;

7. Test method validation to the extent requested by DSHS for each reagent kit provided by the Respondent that will be newly implemented for the life of the

Contract. Respondent shall provide reagent kits and consumables for validation at no additional cost. New test method validation typically includes approximately 250 specimens;

8. Validation conducted on-site at DSHS Laboratory. Reagents and Equipment must pass validation/verification process conducted at DSHS. The process must include studies to determine the accuracy, precision, sensitivity, specificity, reference range, reportable range, and carryover rate of the test method to meet the criteria listed in the or specific acceptance criteria defined by DSHS; and
9. All reagents and Equipment must meet DSHS requirements. If the validation is unacceptable, assist DSHS to perform additional testing to meet DSHS defined requirements. If the validation continues to be unacceptable, DSHS shall reject the reagent kit or Equipment, and the Contract may be terminated.

F. Support/Backup Plan– Under **Form A, Narrative Proposal** describe the Respondent's ability to provide each of the following:

1. Provide a detailed backup plan for ensuring continuity of the of the DSHS NBS CF DNA Testing System during emergency situations affecting DSHS or Respondent. Include resources available to Respondent to assist DSHS and address Equipment, reagent kits, consumables, and software emergencies.
2. Provide back-up testing services in case of emergencies, including information as to test method, CFTR mutations list, specimen shipping and reporting logistics, turnaround time, daily specimen volume capacity, and cost per specimen.

5.1.3 Value-Added Benefits

Using **Form A, Narrative Proposal,** describe any Services or Deliverables that are not required by this Solicitation that the Respondent proposes to provide at no additional cost to HHS. Respondents are not required to propose value-added benefits, but inclusion of such benefits may result in a more favorable evaluation.

5.1.4 Key Staffing Profile

Per **Form A, Narrative Proposal,** Respondent shall provide a key staffing profile and resumes for staff that will be responsible for the performance of the Services requested under this Solicitation.

ARTICLE VI. REQUIRED RESPONDENT INFORMATION

6.1 COMPANY INFORMATION

Respondent shall provide satisfactory evidence of its ability to manage and coordinate the types of activities described in this Solicitation and to produce the specified Goods or Services on time. As a part of the Solicitation Response requested in **Article III, Administrative Information,** Respondent shall provide the following information:

6.1.1 Company Narrative

Per **Form B, Company Information**, Respondent shall provide a detailed narrative explaining why Respondent is qualified to provide the Services enumerated in **Article II, Scope of Work/Specifications,** focusing on its company's key strengths and competitive advantages.

6.1.2 Company Profile

Per **Form B, Company Information** Respondent shall provide a company profile to include:

A. The company ownership structure (corporation, partnership, LLC, or sole proprietorship), including any wholly-owned subsidiaries, affiliated companies, or joint ventures. (*Please provide this information in a narrative and as a graphical representation*). If Respondent is an affiliate of, or has a joint venture or strategic alliance with, another company, Respondent shall identify the percentage of Respondent ownership and the percentage of the parent's ownership. The entity performing the majority of the Work under a Contract, throughout the duration of the Contract, must be the primary bidder. Finally, please provide your proposed operating structure for the Services requested under this Solicitation and which entities (i.e., parent company, affiliate, joint venture, subcontractor) will be performing them;

B. The year the company was founded and/or incorporated. If incorporated, please indicate the state where the company is incorporated and the date of incorporation;

C. The location of company headquarters and any field office(s) that may provide Services for any resulting Contract under this Solicitation;

D. The number of employees in the company, both locally and nationally, and the location(s) from which employees will be assigned;

E. The name, address, and telephone number of Respondent's point of contact for any resulting Contract under this Solicitation; and

F. Indicate whether the company has ever been engaged under a contract by any Texas state agency. If "Yes," specify when, for what duties, and for which agency.

Note: If Respondent is an out-of-state company, a Certificate of Authority from the Texas Secretary of State to do business in Texas must be provided as well.

6.2 REFERENCES

Under **Form B, Company Information** Respondent shall provide a minimum of three (3) references from similar contracts or projects performed, preferably for state and/or local government, within the last seven (7) years. Respondent shall verify current contracts. Information provided shall include:

A. Client name;

B. Contract/project description;

C. Total dollar amount of Contract/project;

D. Key staff assigned to the referenced Contract/project that will be designated for work under this Solicitation; and

E. Client Contract/project manager name, telephone number, fax number, and email address.

6.3 MAJOR SUBCONTRACTOR INFORMATION

Under **Form B, Company Information** Respondent shall identify any major subcontractors whom Respondent intends to utilize in performing fifteen percent (15%) or more of any Contract. Respondent shall indicate whether or not Respondent holds any financial interest in any major subcontractor. It may be required as a condition of award that an authorized officer or agent of each proposed major subcontractor sign a statement to the effect that the subcontractor has read, and shall agree to abide by, Respondent's obligations under any Contract awarded pursuant to this Solicitation.

6.4 LITIGATION AND CONTRACT HISTORY

Respondent shall include in its Solicitation Response a complete disclosure of any alleged or significant contractual failures per **Form C, Entity Information and Contract and Litigation History**. In addition, Respondent shall disclose any civil or criminal litigation or investigation over the last five (5) years that involves Respondent or in which Respondent has been judged guilty or liable including any allegations of such that are currently pending.

Respondent shall also disclose any settlement agreements entered into in the last five (5) years related to alleged contractual failures.

Failure to comply with the terms of this section may disqualify Respondent. Solicitation Response may be rejected based upon Respondent's prior history with the State of Texas or with any other party that demonstrates, without limitation, unsatisfactory performance, adversarial or contentious demeanor, or significant failure(s) to meet contractual obligations.

6.5 CONFLICTS

Respondent shall certify that it does not have any personal or business interests that present a conflict of interest with respect to the RFP and any resulting Contract. Respondent shall use **Form C, Entity Information and Contract and Litigation History.** Additionally, if applicable, the Respondent shall disclose all potential conflicts of interest. The Respondent shall describe the measures it shall take to ensure that there shall be no actual conflict of interest and that its fairness, independence, and objectivity shall be maintained. HHS shall determine to what extent, if any, a potential conflict of interest can be mitigated and managed during the term of the Contract. Failure to identify actual and potential conflicts of interest may result in disqualification of a Solicitation Response or termination of a Contract.

Please include any activities of affiliated or parent organizations and individuals who may be assigned to the Contract, if any.

Additionally, pursuant to the Texas Government Code Section 2252.908, a successful Respondent awarded a Contract with a value of $1 million or more or awarded a Contract that would require the successful Respondent to register as a lobbyist under Texas Government Code Chapter 305 must submit a disclosure of interested parties form to HHS at the time the business entity submits the signed Contract. Rules and filing instructions may be found on the Texas Ethics Commission's public website and additional instructions shall be given by HHSC to successful Respondents.

6.6 AFFIRMATIONS AND CERTIFICATIONS

Respondent shall complete and return all of the following affirmations and certifications:

Exhibit A, HHS Solicitation Affirmations, v 1.7.

6.7 FINANCIAL CAPACITY

Using **Form E, Financial Capacity**, all Respondents shall supply evidence of financial capacity sufficient to demonstrate reasonable stability and solvency appropriate to the requirements of this RFP.

6.7.1 Financial Statements and Financial Solvency

A. Respondent shall submit electronically in a word searchable PDF format an annual report, which must include:

1. Last three (3) years of Audited Financial Statements, including all supplements, management discussion and analysis, and actuarial opinions.
2. If applicable, last three (3) years of consolidated statements for any holding companies or affiliates
3. A full disclosure of any events, liabilities, or contingent liabilities that could affect Respondent's financial ability to perform the Contract.

   At a minimum, such financial statements must include:

   a. Balance sheet,
   b. Income Statement,
   c. Statement of Changes in Financial Position,
   d. Statement of Cash Flows, and
   e. Capital Expenditures.

B. If the Respondent is a corporation that is required to report to the Securities and Exchange Commission (SEC), Respondent shall submit its three (3) most recent SEC Form 10K, Annual Reports, pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Financial materials must be submitted electronically in a word searchable PDF format.

C. If Audited Financial Statements are not available, Respondent shall submit unaudited financial information and any other information the Respondent believes meets the requirements of this section. See **Section 6.7.2, Alternate Report**. If the submitted

documents do not provide adequate assurance of financial stability or solvency, HHSC reserves the right to request additional information or to disqualify the Respondent.

D. Substantial Ownership or Wholly Owned by another Corporate Entity. If the Respondent is either substantially or wholly owned by another corporate (or legal) entity, the Respondent shall include the information required in this **Section 6.7.1** for each such entity, including the most recent detailed financial report for each such entity.

E. If HHS determines that an entity does not have sufficient financial resources to guarantee the Respondent's performance, HHS may require the Respondent to obtain another acceptable financial instrument or resource from such entity, or to obtain an acceptable guarantee from another entity with sufficient financial resources to guarantee performance.

6.7.2 Alternate Report

A. If Respondent(s) is unable to provide the annual report specified above, Respondent(s) may, at the discretion of HHS, provide the following alternate report:

B. Last three (3) years un-audited financial statements, including all supplements, management discussion and analysis, and actuarial opinions.;

C. An un-audited financial statement of the most recent quarter of operation; and

D. A full disclosure of any events, liabilities, or contingent liabilities that could affect Respondent's financial ability to perform the Contract.

At a minimum, such financial statements must include:

1. Balance sheet,
2. Income Statement,
3. Statement of Changes in Financial Position,
4. Statement of Cash Flows, and
5. Capital Expenditures.

6.8 CORPORATE GUARANTEE

Per **Form B, Company Information** if the Respondent is substantially owned or controlled, in whole or in part, by one or more other legal entities, the Respondent shall submit the information required under **Section 6.7, Financial Capacity** for each such entity, including the most recent financial statement for each such entity. The Respondent shall also include a statement that the entity or entities shall unconditionally guarantee performance by the Respondent of each and every obligation, warranty, covenant, term, and condition of the Contract. If HHSC determines that an entity does not have sufficient financial resources to guarantee the Respondent's performance, HHSC may require the Respondent to obtain another acceptable financial instrument or resource from such entity, or to obtain an acceptable guarantee from another entity with sufficient financial resources to guarantee performance.

6.9 HUB SUBCONTRACTING PLAN

Submit the HUB Subcontracting Plan (HSP) in accordance with **Section 3.7.2, Submission Options**, labeled: "HUB Subcontracting Plan (HSP)," and include all supporting documentation in accordance with **Exhibit F, HUB Subcontracting Plan**.

ARTICLE VII. COST PROPOSAL

7.1 COST PROPOSAL

As noted above in **Section 3.7.2, Submission Options**, cost information must not be included with the Respondent's Narrative Proposal. Respondent shall submit a cost proposal for the Services listed in **Article II, Scope of Work/Specifications** on **Form D, Cost Proposal** provide in this RFP. All fields of the Cost Proposal need to be completed.

7.1.1 Cost Proposal Details

A. The amounts listed on the Cost Proposal must include all costs necessary to provide the products and Services according to the minimum specifications, requirements, provisions, terms, and conditions set forth in this RFP.

B. Cost Proposal must include the fees for reagent kits and consumables and must be inclusive of Equipment rental, maintenance and service. Respondent shall authorize DSHS to use Respondent provided and installed Equipment.

C. Cost Proposal must include item part number, item description, unit quantity, unit cost, estimated annual quantity and extended cost.

D. All items to be provided with this Cost Proposal must be listed, including analytical reagent kits, consumables, supply and Equipment parts, test Equipment, back-up testing Services, stations, operating system, and Equipment database maintenance, support, and training. Contractor shall be responsible for the payment of any fee, tax, tariff or other charge however called, imposed by any federal, state, or local government or any regulatory authority or third party with respect to the performance of any service or delivery of any product or material by Respondent pursuant to the Contract. Do not provide such in the Cost Proposal. If included, any of these proposed items shall be rejected and not included in the resulting Contract.

E. All Equipment required to perform dried blood spot specimen preparation and DNA extraction (if required or recommended by the kit manufacturer) shall be supplied by the Respondent as part of the reagent rental at no additional cost. However, reagents necessary for DNA extraction do not have to be provided by the Respondent and may be purchased separately by DSHS.

F. All Equipment and/or reagents needed for DNA quantification (if required or recommended by the kit manufacturer) shall be provided by the Respondent at no additional cost.

G. All Equipment required for testing shall be supplied by the Respondent at no additional cost.

7.1.2 Value-Added Benefits

Respondent shall separately identify value-added benefits, cost-savings and cost-avoidance methods and measures, and the effect of such methods on the Cost Proposal and Scope of Work/Specifications.

ARTICLE VIII. GENERAL TERMS AND CONDITIONS

8.1 GENERAL CONDITIONS

8.1.1 Amendment

HHS reserves the right to alter, amend, or modify any provision of this Solicitation, or to withdraw this Solicitation, at any time prior to award, if it is in the best interest of the State.

8.1.2 Offer Period

Solicitation Responses shall be binding for a period of 240 days after the due date for submission of Solicitation Responses. Each Respondent may extend the time for which its Solicitation Response shall be honored. Upon Contract execution, prices agreed upon by the Respondent(s) are an irrevocable offer for the term of the Contract and any Contract renewals or extension(s). No other costs, rates, or fees shall be payable to the Respondent unless expressly agreed upon in writing by HHS.

8.1.3 Costs Incurred

Respondents understand that issuance of this Solicitation in no way constitutes a commitment by HHS to award a Contract or to pay any costs incurred by a Respondent in the preparation of a response to this Solicitation. HHS is not liable for any costs incurred by a Respondent prior to issuance of or entering into a formal agreement, Contract, or purchase order. Costs of developing Solicitation Responses, preparing for or participating in oral presentations and site visits, or any other similar expenses incurred by a Respondent are entirely the responsibility of the Respondent, and will not be reimbursed in any manner by the State of Texas.

8.1.4 Contract Responsibility

The System Agency shall look solely to Respondent for the performance of all contractual obligations that may result from an award based on this Solicitation. Respondent shall not be relieved of its obligations for any nonperformance by its Subcontractors.

8.1.5 Public Information Act - Respondent Requirements Regarding Disclosure

Proposals and contracts are subject to the Texas Public Information Act (PIA), Texas Government Code Chapter 552, and may be disclosed to the public upon request. Other legal authority also requires System Agency to post contracts and proposals on its public website and to provide such information to the Legislative Budget Board for posting on its public website.

Under the PIA, certain information is protected from public release. If Respondent asserts that information provided in its Solicitation Response is exempt from disclosure under the PIA, Respondent shall:

A. Mark Original Proposal:

1. Mark the Original Proposal, on the top of the front page, the words "CONTAINS CONFIDENTIAL INFORMATION" in large, bold, capitalized letters (the size of, or equivalent to, 12-point Times New Roman font or larger); and

2. Identify, adjacent to each portion of the Solicitation Response that Respondent claims is exempt from public disclosure, the claimed exemption from disclosure (NOTE: no redactions are to be made in the Original Proposal);

B. Certify in Original Proposal – HHS Solicitation Affirmations, v 1.7 (attached as Exhibit A to this Solicitation):

C. Certify, in the designated section of the Affirmations and Solicitation Acceptance, Respondent's confidential information assertion and the filing of its Public Information Act Copy; and

D. Submit Public Information Act Copy of Proposal:

Submit a separate "Public Information Act Copy" of the Original Proposal (in addition to the original and all copies otherwise required under the provisions of this Solicitation). The Public Information Act Copy must meet the following requirements:

1. The copy must be clearly marked as "Public Information Act Copy" on the front page in large, bold, capitalized letters (the size of, or equivalent to, 12-point Times New Roman font or larger);

2. Each portion Respondent claims is exempt from public disclosure must be redacted (blacked out); and

3. Respondent shall identify, adjacent to each redaction, the claimed exemption from disclosure. Each identification provided as required in Subsection (C) of this section must be identical to those set forth in the Original Proposal as required in Subsection (A)(2), above. The only difference in required markings and information between the Original Proposal and the Public Information Act Copy of the proposal will be redactions - which can only be included in the Public Information Act Copy. There must be no redactions in the Original Proposal.

By submitting a response to this Solicitation, Respondent agrees that, if Respondent does not mark the Original Proposal, provide the required certification in the Affirmations and Solicitation Acceptance, and submit the Public Information Act Copy, Respondent's proposal will be considered to be public information that may be released to the public in any manner including, but not limited to, in accordance with the Public Information Act, posted on the System Agency's public website, and posted on the Legislative Budget Board's public website.

If any or all Respondents submit partial, but not complete, information suggesting inclusion of confidential information and failure to comply with the requirements set

forth in this section, System Agency, in its sole discretion and in any solicitation, reserves the right to (1) disqualify all Respondents that fail to fully comply with the requirements set forth in this section, or (2) to offer all Respondents that fail to fully comply with the requirements set forth in this section additional time to comply.

Respondent should not submit a Public Information Act Copy indicating that the entire proposal is exempt from disclosure. Merely making a blanket claim that the entire proposal is protected from disclosure because it contains any amount of confidential, proprietary, trade secret, or privileged information is not acceptable, and may make the entire proposal subject to release under the PIA.

Proposals should not be marked or asserted as copyrighted material. If Respondent asserts a copyright to any portion of its proposal, by submitting a proposal, Respondent agrees to reproduction and posting on public websites by the State of Texas, including the System Agency and all other state agencies, without cost or liability.

The System Agency shall strictly adhere to the requirements of the PIA regarding the disclosure of public information. As a result, by participating in this solicitation process, Respondent acknowledges that all information, documentation, and other materials submitted in the proposal in response to this Solicitation may be subject to public disclosure under the PIA. The System Agency does not have authority to agree that any information submitted will not be subject to disclosure. Disclosure is governed by the PIA and by rulings of the Office of the Texas Attorney General. Respondents are advised to consult with their legal counsel concerning disclosure issues resulting from this process and to take precautions to safeguard trade secrets and proprietary or otherwise confidential information. The System Agency assumes no obligation or responsibility relating to the disclosure or nondisclosure of information submitted by Respondents.

For more information concerning the types of information that may be withheld under the PIA or questions about the PIA, please refer to the Public Information Act Handbook published by the Office of the Texas Attorney General or contact the attorney general's Open Government Hotline at (512) 478-OPEN (6736) or toll-free at (877) 673-6839 (877-OPEN TEX). To access the Public Information Act Handbook, please visit the attorney general's website at http://www.texasattorneygeneral.gov.

8.1.6 Respondent Waiver – Intellectual Property

SUBMISSION OF ANY DOCUMENT TO ANY HHS AGENCY IN RESPONSE TO THIS SOLICITATION CONSTITUTES AN IRREVOCABLE WAIVER, AND AGREEMENT BY THE SUBMITTING PARTY TO FULLY INDEMNIFY THE STATE OF TEXAS, HHSC OR DSHS FROM, ANY CLAIM OF INFRINGEMENT BY HHSC OR DSHS REGARDING THE INTELLECTUAL PROPERTY RIGHTS OF THE SUBMITTING PARTY OR ANY THIRD PARTY FOR ANY MATERIALS SUBMITTED TO HHS BY THE SUBMITTING PARTY.

8.2 INSURANCE

8.2.1 Required Coverage

For the duration of any Contract resulting from this Solicitation, Respondent shall acquire insurance, bonds, or both, if applicable with financially sound and reputable independent insurers, in the type and amount customarily carried within the industry. Failure to maintain insurance coverage or acceptable alternative methods of insurance shall be deemed a breach of Contract.

8.2.2 Alternative Insurability

Notwithstanding the preceding, the System Agency reserves the right to consider reasonable alternative methods of insuring the Contract in lieu of the insurance policies customarily required. It shall be the Respondent's responsibility to recommend to the System Agency alternative methods of insuring the Contract. Any alternatives proposed by Respondent should be accompanied by a detailed explanation regarding Respondent's inability to obtain the required insurance and/or bonds. The System Agency shall be the sole and final judge as to the adequacy of any substitute form of insurance coverage.

8.3 PROTEST

If a Respondent wishes to file a protest they may do so in accordance with the rules published by HHSC in the Texas Administrative Code, Title 1, Part 15, Chapter 391, Subchapter D, Protests.

ARTICLE IX. SUBMISSION CHECKLIST

This checklist must be read carefully as it identifies documents that are requested in this Solicitation.

Solicitation Consideration and Award Consideration Documents, reference **Section 1.2, Definitions,** must be submitted by the deadline for Solicitation Response submissions, reference **Section 3.1, Schedule of Events**. Solicitation Consideration Documents will be reviewed as-is, without any opportunity to remedy missed requirements. HHS, at its sole discretion, may request some or all of the Respondents to remedy missing elements of Award Consideration Documents.

Original Solicitation Response Package

The Solicitation Package must include the Solicitation Response in one of the approved submission methods identified in **Section 3.7.2, Submission Options**. Those marked "SC" are Solicitation Consideration Documents and those marked "AC" are Award Consideration Documents. See next page.

A.	**Proposal and Respondent Information**			
1.	Narrative Proposal	(Section 5.1 and Form A)	SC	____
2.	Company Information	(Section 6.1 and Form B)	SC	____
3.	References	(Section 6.2 and Form B)	SC	____
4.	Major Subcontractor Information	(Section 6.3 and Form B)	SC	____
5.	Litigation and Contract History	(Section 6.4 and Form C)	AC	____
6.	Conflicts	(Section 6.5 and Form C)	AC	____
7.	Affirmations and Certifications	(Section 6.6, Exhibits A and Exhibit D-1)	SC	____
8.	Minimum Qualifications	(Section 4.1.2 and Form B)	SC	____
9.	Exceptions	(Section 3.7.4 and Exhibit E)	AC	____
10.	Assumptions (if applicable)	(Section 3.7.5 and Exhibit K)	AC	____
11.	Financial Capacity	(Section 6.7.2 and Form E)	AC	____
12.	Corporate Guarantee	(Section 6.8 and Form B)	AC	____
B.	**Cost Proposal**	(Article VII and Form D)	SC	____
C.	**HUB Subcontracting Plan**	(Section 6.9 and Exhibit F)	SC	____

ARTICLE X. LIST OF EXHIBITS AND FORMS

EXHIBIT A, HHS SOLICITATION AFFIRMATIONS V 1.7

EXHIBIT B, HHS UNIFORM TERMS AND CONDITIONS – VENDOR, V 3.2

EXHIBIT C, HHS ADDITIONAL PROVISIONS, V 1.0

EXHIBIT D, DATA USE AGREEMENT (DUA)

EXHIBIT D-1, ATTACHMENT 2 TO THE DUA, SECURITY AND PRIVACY INQUIRY (SPI)

EXHIBIT E, EXCEPTIONS FORM

EXHIBIT F, HUB SUBCONTRACTING PLAN

EXHIBIT G, EVALUATION TOOL

EXHIBIT H, SIGNATURE DOCUMENT TEMPLATE

EXHIBIT I, HHS ONLINE BID ROOM

EXHIBIT J, CONTRACT AFFIRMATIONS

EXHIBIT K, ASSUMPTIONS FORM

FORM A, NARRATIVE PROPOSAL

FORM B, COMPANY INFORMATION

FORM C, ENTITY INFORMATION CONFLICTS AND CONTRACT AND LITIGATION HISTORY

FORM D, COST PROPOSAL

FORM E, FINANCIAL CAPACITY

Please note that some exhibits have a separate cover page from the body of the document. Please review both documents.