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**SIGNATURE DOCUMENT FOR
DEPARTMENT OF STATE HEALTH SERVICES
CONTRACT NO. HHS000688500001**

</div>

I. PURPOSE

The **DEPARTMENT OF STATE HEALTH SERVICES** ("**SYSTEM AGENCY**"), an administrative agency within the executive department of the State of Texas and having its principal office at 1100 West 49th Street, Austin, Texas, and **PERKINELMER HEALTH SCIENCES, INC.** ("**CONTRACTOR**"), having its principal office at 710 Bridgeport Avenue, Shelton, Connecticut (each a "Party" and collectively "the Parties") enter into the following contract for Newborn Screening ("NBS") goods and services (the "Contract").

II. LEGAL AUTHORITY

This Contract is authorized by and in compliance with the provisions of Title 10, Subtitle D of the *Texas Government Code*, in particular, *Texas Government Code* Sections 531.039 and 2155.144; and *Texas Health and Safety Code* Section 12.051.

III. STATEMENT OF SERVICES TO BE PROVIDED

Contractor shall perform or cause to be performed the Services in accordance with the **STATEMENT OF WORK** and **PRICE LIST**, attached hereto and incorporated herein as **ATTACHMENTS A AND B**, respectively.

IV. DURATION

The Contract is effective on **September 1, 2020** and terminates on **August 31, 2022**, unless sooner terminated or renewed or extended. System Agency, at its sole discretion, may renew or extend this 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 beyond 5 years as necessary to ensure continuity of service, for purposes of transition, or as otherwise determined by System Agency to serve the best interests of the State.

V. BUDGET

The amount of this Contract for Fiscal Year (FY) 2021 will not exceed **$19,644,604.00** and the amount of this Contract for FY 2022 will not exceed **$18,915,223.00**. The total amount of this Contract will not exceed **$38,559,827.00**. All expenditures under the Contract will be in accordance with **ATTACHMENT B, PRICE LIST**.

VI. CONTRACT REPRESENTATIVES

The following will act as the Representative authorized to administer activities under this Contract on behalf of their respective Party.

SYSTEM AGENCY
Department of State Health Services
P.O. Box 149347 – Mail Code 1990
Austin, Texas 78714-9347
Attention: Caeli Paradise

CONTRACTOR
PerkinElmer Health Sciences, Inc.
710 Bridgeport Ave.
Shelton, Connecticut 06484-4750
Attention: Dawn Mercer

VII. **NOTICE REQUIREMENTS**

A. All notices given by Contractor shall be in writing, include the Contract number, comply with all terms and conditions of the Contract, and be delivered to the System Agency's Contract Representative identified above.

B. Contractor shall send legal notices to System Agency at the address below and provide a copy to the System Agency's Contract Representative:

> Health and Human Services Commission
> Attn: Office of Chief Counsel
> 4900 N. Lamar Blvd.
> Austin, Texas 78751
>
> **With copy to**
>
> Department of State Health Services
> P.O. Box 149347 – Mail Code 1911
> Austin, Texas 78714-9347
> Attention: General Counsel

C. System Agency shall send legal notices to Contractor at the address below and provide a copy to the Contractor's Contract Representative:

> PerkinElmer, Inc.
> 940 Winter Street
> Waltham, MA 02451
> Attn: General Counsel-DX
> With a copy to: LegalNotices@perkinelmer.com

D. Notices given by System Agency to Contractor may be emailed, mailed or sent by common carrier. Email notices shall be deemed delivered when sent by System

Agency. Notices sent by mail shall be deemed delivered when deposited by the System Agency in the United States mail, postage paid, certified, return receipt requested. Notices sent by common carrier shall be deemed delivered when deposited by the System Agency with a common carrier, overnight, signature required.

E. Notices given by Contractor to System Agency shall be deemed delivered when received by System Agency.

F. Either Party may change its Contract Representative or Legal Notice contact by providing written notice to the other Party.

VIII. **ATTACHMENT C, UNIFORM TERMS AND CONDITIONS (VERSION 3.0) ("UTCS"),** of the Contract is revised as follows. Unless expressly modified, amended, or replaced in this Section, the UTCs shall remain in full force and effect:

- **Section 5.2, Subsection B** of the UTCs, is deleted in its entirety and replaced with the following:

  B. Contractor hereby grants to System Agency an irrevocable, perpetual, non-exclusive, royalty-free, transferable, worldwide right and license, with the right to sublicense and to use the Incorporated Pre-existing Works, in connection with its use of the associated Work Product.

- **Section 9.4** of the UTCs is deleted in its entirety and replaced with the following:

  If the System Agency terminates the Contract for cause, the Contractor may be found responsible to the System Agency for all excess costs incurred by the System Agency and the State of Texas to replace the Contractor.

IX. **LIMITATION OF LIABILITY**

CONTRACTOR, ITS SUBCONTRACTORS AND THEIR RESPECTIVE PERSONNEL SHALL NOT BE LIABLE TO SYSTEM AGENCY FOR ANY CLAIMS, LIABILITIES OR ASSOCIATED EXPENSES RELATED TO THIS CONTRACT ("CLAIMS") IN AN AGGREGATE AMOUNT IN EXCESS OF THE SUM EQUAL TO THREE (3) TIMES THE TOTAL OF THE AMOUNTS PAID TO CONTRACTOR FOR THE PRODUCTS AND SERVICES SOLD UNDER THE CONTRACT IN THE CONTRACT YEAR IN WHICH THE CLAIM, LIABILITY OR ASSOCIATED EXPENSES AROSE. NEITHER PARTY WILL BE LIABLE TO THE OTHER FOR ANY EXEMPLARY OR PUNITIVE DAMAGES UNDER ANY CONTRACT, TORT (INCLUDING NEGLIGENCE), OR OTHER LEGAL THEORY. THIS LIMITATION WILL APPLY REGARDLESS OF THE CAUSE OF ACTION AND EVEN IF A PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, PROVIDED, HOWEVER, THAT THE FOREGOING LIMITATIONS AND EXCLUSIONS SHALL NOT APPLY TO, AND CONTRACTOR WILL FULLY INDEMNIFY SYSTEM AGENCY FOR, THE FOLLOWING:

    i.   **CLAIMS RESULTING FROM CONTRACTOR'S OR ITS SUBCONTRACTORS' RECKLESSNESS, BAD FAITH OR INTENTIONAL MISCONDUCT;**

    ii.   **CLAIMS FOR PERSONAL INJURY (INCLUDING DEATH) AND PROPERTY DAMAGE;**

    iii.   **VIOLATION OF INTELLECTUAL PROPERTY RIGHTS INCLUDING BUT NOT LIMITED TO PATENT, TRADEMARK, COPYRIGHT INFRINGEMENT, OR TRADE SECRET;**

    iv.   **CLAIMS RESULTING FROM VIOLATIONS BY CONTRACTOR RESULTING IN A BREACH OF CONFIDENTIAL INFORMATION, INCLUDING FAILURE TO SAFEGUARD CONFIDENTIAL INFORMATION AS REQUIRED IN ATTACHMENT F, DATA USE AGREEMENT.**

EACH PARTY HAS A DUTY TO MITIGATE THE DAMAGES THAT WOULD OTHERWISE BE RECOVERABLE FROM THE OTHER PARTY PURSUANT TO THIS CONTRACT BY TAKING SUCH ACTIONS AS MAY BE REQUIRED UNDER TEXAS LAW TO REDUCE OR LIMIT THE AMOUNT OF SUCH DAMAGES.

X. CONTRACT DOCUMENTS

The following documents are incorporated by reference and made a part of this Contract for all purposes.

Unless expressly stated otherwise in this Contract, in the event of conflict, ambiguity or inconsistency between or among any documents, all System Agency documents take precedence over Contractor's documents and the Data Use Agreement takes precedence over all other Contract documents.
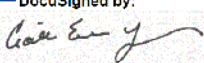
ATTACHMENT A - STATEMENT OF WORK
ATTACHMENT B - PRICE & EQUIPMENT LIST
ATTACHMENT C - UNIFORM TERMS AND CONDITIONS (VERSION 3.0)
ATTACHMENT D - CONTRACT AFFIRMATIONS (VERSION 1.6)
ATTACHMENT E - HHS ADDITIONAL PROVISIONS
ATTACHMENT F - DATA USE AGREEMENT (VERSION 8.5)
ATTACHMENT G - SECURITY AND PRIVACY INQUIRY (SPI)
ATTACHMENT H - SOFTWARE LICENSING AGREEMENT
ATTACHMENT I - UNDERTAKING AND GUARANTY
ATTACHMENT J - SOFTWARE SUPPORT TERMS AND CONDITIONS
ATTACHMENT K - BACKUP PLAN

SIGNATURE PAGE FOLLOWS

SIGNATURE PAGE FOR SYSTEM AGENCY CONTRACT NO. HHS000688500001
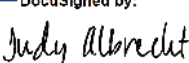
DEPARTMENT OF STATE HEALTH SERVICES

PERKINELMER HEALTH SCIENCES, INC.

Cecile Erwin Young

Judy Albrecht

Executive Commissioner

Assistant Secretary

Date of execution: August 20, 2020

Date of execution: August 20, 2020

ATTACHMENTS FOLLOW

ATTACHMENT A
STATEMENT OF WORK

I. DEFINITIONS

"Analytical Testing" means laboratory analysis performed on specimens submitted by healthcare providers.

"Change Management Board" consists of one representative from each of DSHS IT Application Development, DSHS IT Operations, IT Security, DSHS Lab and the Contractor. They meet on a regular basis to review and approve any changes to LIMS prior to implementation.

"Consumables" means items required for running an assay that are used during the process and must be routinely replaced. Some consumable supplies are parts required for equipment operation (*such as microtiter plates, pipet tips, dilution vessels, and isoelectric focusing wicks*), while others are used to prepare kit components or testing reagents for analytical use (*such as blotting paper*). Consumable supplies may be a component of the testing reagent or may be a separately acquired item.

"Health Level 7 (HL7)" means an international framework (*and related standards*) for the exchange, integration, sharing, and retrieval of electronic health information.

"Laboratory Information Management System" or "LIMS" means laboratory software capable of maintaining data on the entire newborn screening process start with the specimen collection kits inventory and distribution through the specimen testing and follow-up of abnormal results including billing Medicaid and healthcare providers.

"Newborn Screening (NBS) Panel of Disorders" In Texas disorders being tested for are inclusive of the Recommend Uniform Screening Panel, which are core and secondary conditions detectable through blood spot screening, as recommended by the Advisory Committee on Heritable Disorders in Newborns and Children and approved by the Secretary of Health and Human Services that are in place as of September 2019. The current list of fifty-four (54) disorders screened in Texas by DSHS is located on the DSHS internet website at: https://www.dshs.state.tx.us/newborn/quickreference.shtm.

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

"Submitter" means a physician, birthing facility or healthcare provider who orders specimen collection kits to collect specimens on newborns and returns the kit to the laboratory for newborn screening.

II. CONTRACTOR RESPONSIBILITES

2.1 For the NBS Panel of Disorders and additional testing with the current testing algorithm (as of September 2019), Contractor must provide the following:

A. Testing reagents with ongoing training and technical support on testing methodologies;

B. Consumables, including assay required items and equipment required parts;

C. Equipment, including service, maintenance, upgrades, and parts. Equipment must fit within the current DSHS location and space;

D. Four (4) full-time qualified field service personnel to provide maintenance and support for the test equipment and systems. Field service personnel must be located onsite at the DSHS NBS Laboratory daily Monday through Saturday;

E. Qualified technical support personnel, including tandem mass spectrometry (MS/MS) specialists, to assist with equipment normalization and optimization, development of test methods, and programing assay method files for LIMS interface, and to ensure assay performance and analytical validity of the testing;

F. LIMS software capable of maintaining data on specimen collection kit inventory and distribution, specimen receipt, analytical testing, assay quality control monitoring, result reporting, clinical care coordination activities, and billing; and

G. Full-time qualified LIMS engineer located onsite at the DSHS NBS Laboratory daily Monday through Friday to provide LIMS maintenance, support, and technical assistance.

H. Contractor will perform all services and create, receive, maintain, use disclose or have access to confidential information solely with the United States of America. This includes providing customer service, maintenance and technical support related to IT hardware, software, and data. This does not include providing goods related to testing reagents, consumables, or testing equipment.

2.1.1 Contractor must provide, at a minimum, testing reagents and consumables, equipment, interface to LIMS, and LIMS - with associated analytes, tested by MS/MS and other technologies, for the disorders listed in **Table 1.**

Table 1

2 Methylbutyrylglycinuria (2MBG) – C5
2,4 Dienoyl-CoA Reductase Deficiency (DE RED) – C10:2
2-Methyl-3-Hydroxybutyric Aciduria (2M3HBA) – C5OH, C6DC, C5:1
3-Methylcrotonyl-CoA carboxylase deficiency (3MCC) - C5OH, C6DC, C5:1
3-Methylglutaconic Aciduria (3MGA) – C5OH, C6DC, C5:1

Argininemia (ARG) – arginine
Argininosuccinic acidemia (ASA) – citrulline
Benign Hyperphenylalaninemia (H-PHE) – phenylalanine, phe/tyr ratio
Biopterin defect in cofactor biosynthesis (BIOPT BS) – phenylalanine, phe/try ratio
Biopterin defect in cofactor regeneration (BIOPT REG) – phenylalanine, phe/tyr ratio
Carnitine Acylcarnitine Translocase Deficiency (CACT) – C16, C18:1, C14
Carnitine Palmitoyltransferase Type I Deficiency (CPT IA) – C0, C0/(C16+C18)
Carnitine Palmitoyltransferase Type II Deficiency (CP II) – C16
Carnitine uptake defect (CUD) – C0, C3 + C16
Citrullinemia (CIT) – citrulline
Citrullinemia, Type II (CIT II) – citrulline
Congenital adrenal hyperplasia (CAH) -17-OH-progesterone (17-OHP)
Congenital hypothyroidism - T4, thyroid stimulating hormone (TSH)
Cystic Fibrosis (CF) - immuno-reactive trypsinogen (IRT)
Galactosemia - Gal-1-PO4 uridyltransferase (GALT)
Glutaric acidemia type I (GA I) – C5DC
Glutaric Acidemia Type II (GA2) – C4, C5
Homocystinuria – due to CBS deficiency (HCY) - methionine
Hydroxymethylglutaric aciduria (HMG) – C5OH, C6DC
Hypermethioninemia (MET) – methionine
Isobutyrylglycinuria (IBG) – C4
Isovaleric acidemia (IVA) – C5
Long-chain hydroxyacyl-CoA dehydrogenase deficiency (LCHAD) – C16OH, C18OH, C16:1OH, C18:1OH, C18:2OH
Malonic Acidemia (MAL) - C3DC
Malonic Acidemia (MAL) - C3DC
Maple syrup urine disease (MSUD) – leucine, valine
Medium/Short Chain L-3-Hydroxyacyl-CoA Dehydrogenase Deficiency (M/SCHAD) – C4OH
Medium-chain acyl-CoA dehydrogenase deficiency (MCAD) C8, C6, C10, C10:1, C8/C2 ratio
Medium-Chain Ketoacyl-CoA Thiolase Deficiency (MCKAT) – C8
Methylmalonic acidemia – mutase deficiency (MUT) – C3, C3/C2 ratio
Methylmalonic acidemia -cobalamin A and B form (MMA Cbl A, B) – C3, C3/C2 ratio
Methylmalonic Acidemia with Homocystinuria (Cbl C, D) - C3, C3/C2
Multiple carboxylase deficiency (MCD) – C5OH, C6DC, C5:1
Phenylketonuria (PKU) – phenylalanine, phe/tyr ratio
Propionic acidemia (PROP) – C3, C3/C2 ratio
Short-Chain Acyl-CoA Dehydrogenase Deficiency (SCAD) – C4, C4/C2
Trifunctional protein deficiency (TFP) - C16OH, C18OH, C16:1OH, C18:1OH, C18:2OH
Tyrosinemia type I (TYR I) - succinylacetone
Tyrosinemia, Type II (TYR II) – tyrosine
Tyrosinemia, Type III (TYR III) – tyrosine
Very long-chain acyl-CoA dehydrogenase deficiency (VLCAD) - C14:1. C14, C14:2 C14/C2 ratio
X-linked adrenoleukodystrophy (X-ALD) – C26:0LPC

β-Ketothiolase deficiency (BKT) C5:1

2.1.2 Contractor must provide testing reagents and consumables, equipment interface to LIMS, if applicable, and LIMS for the following disorder, with associated analytes, tested by DSHS-owned equipment:

Hemoglobinopathies - Hemoglobins S, C, D, G, E, O-Arab, Barts, "Other" variants and indicating beta thalassemia – DSHS owns isoelectric focusing electrophoresis equipment including LKB Multiphor II and Migele gel electrophoresis

2.1.3 Contractor must provide equipment for current DSHS process, equipment interface to LIMS, if applicable, and LIMS for the following disorder, with associated analytes, tested by DSHS-owned testing reagents and consumables:

Biotinidase deficiency - biotinidase – DSHS uses a colorimetric assay to determine biotinidase enzyme activity

2.1.4 Contractor must provide equipment interface to LIMS, if applicable, and LIMS for the following disorders, with associated analytes, tested by DSHS-owned equipment and testing reagents and consumables:

A. Severe Combined Immunodeficiency (SCID) - T-cell Receptor Excision Circle (TREC) – DSHS owns equipment including Beckman Biomek i5 for Deoxyribonucleic acid (DNA) extraction and Thermo Fisher QuantStudio 12K Flex for real-time quantitative PCR to determine TREC copy numbers;

B. Hemoglobinopathy High Performance Liquid Chromatography (Hb-HPLC) Testing using DSHS-owned Bio-Rad VARIANT NBS equipment;

C. Cystic Fibrosis – Deoxyribonucleic Acid (CF-DNA) Testing by CFTR Luminex 60 Mutation Panel using Luminex 200 equipment;

D. Congenital Adrenal Hyperplasia Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS Testing) – DSHS owns Waters TQD equipment;

E. X-linked Adrenoleukodystrophy LC-MS/MS testing– DSHS owns Waters TQD equipment.

2.1.5 Contractor must provide LIMS to support the following additional testing:

Table 2

PKU Monitoring (PKUM) by MS/MS
Hemoglobinopathy DNA Testing by allelic discrimination real-time PCR
Galactosemia DNA Testing by amplification refractory mutation system PCR

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MCAD DNA Testing by allelic discrimination real-time PCR
VLCAD DNA Testing by Sanger sequencing
X-linked Adrenoleukodystrophy DNA Testing by Sanger sequencing

2.2 Testing Reagents and Consumables

2.2.1 Contractor must provide the analytical testing reagents and associated consumables, including assay/method validation, assay technical troubleshooting and problem resolution, related to testing for the current panel of tests, at a minimum, as described in Section 2.1. Contractor must provide a link to all testing reagent kit package inserts.

2.2.2 Contractor must provide the following testing reagents and consumables that meet the following requirements:

    A. United States Food and Drug Administration (FDA) approved testing reagents, for disorders that are currently being tested using an FDA reagent kit, including T4, TSH, GALT, IRT, 17-OH-progesterone, Hemoglobinopathies, and metabolic disorders and X-ALD performed by MS/MS;

    B. MS/MS testing reagents that allow for simultaneous preparation and simultaneous measurement of succinylacetone, specific amino acids and acylcarnitines, and specific lysophospholipids; and

    C. All consumables required by the testing reagents provided by the Contractor.

2.2.3 Contractor must provide testing reagents that meet the following requirements:

    A. The testing reagent kit must utilize a single 3.2mm (1/8") disk punched from dried blood spotted on filter paper cleared by FDA for blood sample collection and manufactured according to the Clinical & Laboratory Standards Institute (CLSI) specifications outlined in the NBS01 document;

    B. Hemoglobinopathy testing reagent kit must also allow for option to utilize a 4.7mm (3/16") disk punched from dried blood spotted on filter paper cleared by FDA for blood sample collection and manufactured according to the Clinical & Laboratory Standards Institute (CLSI) specifications outlined in the NBS01 document;

    C. Analysis must be performed in a 96-well microtiter plate. If coated microtiter products are included, they must be manufactured such that every plate is coated, and that the coating concentration is both adequate and uniform. A barcode (*unique identifier*) or the capability to produce a barcode must be provided for all microtiter plates. Non-coated, partially coated, or incorrectly coated plates must result in the Contractor replacing the testing reagent kits at no charge; and

    D. The testing reagent kit must be FDA approved for clinical assessment of human dried blood spot specimens. Testing reagent kits must meet all applicable US

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Department of Transportation, Code of Federal Regulations, Title 49. Human blood used in the preparation of standards and controls must be negative for the antibody to HIV and non-reactive for Hepatitis B-surface antigen when tested with licensed testing reagents.

2.2.4 Contractor must provide written notification to all the DSHS NBS Laboratory Managers a maximum of ten (10) calendar days after Contractor's knowledge of any change to the reagent kit or to the package insert. Contractor must also provide written notice of the change with the delivery of the reagent kit. Such notification must be visually easy to identify or locate. Failure to meet this requirement may result in rejection of the newly changed reagent kits and Contractor must replace them with reagent kits not affected by the change at no cost to DSHS.

2.2.5 Contractor must supply testing reagents as a single lot for a minimum of four (4) months. DSHS NBS Laboratory reserves the right to increase or decrease the amount of testing reagents orders based on specimen volume. DSHS will inform the Contractor of any change to the testing reagents supply amount at least fifteen (15) calendar days prior to requesting the next shipment. The Contractor must provide new lots of testing reagents at least one (1) month in advance of usage to allow DSHS to conduct an in-house quality control assessment which includes establishment of DSHS in-house control means and appropriate standard deviation (SD) ranges per Clinical Laboratory Improvement Act (CLIA) requirements prior to live specimen testing. The CLIA requirements can be found at the following location:

http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=/clia/
(*Subpart K--Quality System for Nonwaived Testing, D5469 §493.1256 Standard: Control procedures*).

2.2.6 Contractor must provide calibrator lots independent of reagent lots.

2.2.7 Contractor must utilize the Assay, Reagent, and Consumable Supply Problem Resolution Steps. The Contractor must use this process if any change in the quality of consumable supplies or noted manufacturing errors, cause assay or equipment problems and can affect assay performance. For example: cracked, broken, warped, or incorrectly molded dilution vessels, microtiter plates or pipette tips, a change in consistency of blotting paper or wicks used in isoelectric focusing testing, discrepancy between stated fill volume of testing reagents and actual volume, or change in visual appearance of a reagent or consumable. Assay, Reagent, and Consumable Supply Problem Resolution Steps must include at minimum:

A. DSHS must be immediately notify the Contractor by telephone and/or email;

B. Upon notification of a problem, the Contractor must provide a written complaint registration confirmation, initiate an investigation, and provide routine status updates until the problem is identified and resolved;

C. Contractor must provide a written complaint final summary documenting, at a minimum, investigative actions and outcomes within one (1) week of issue resolution;

D. Contractor must provide valid products (*i.e., testing reagents or consumable supplies*) within two (2) weeks to assure testing continuity; and

E. Contractor must provide at no charge, replacement testing reagents and consumable supplies for those identified as unusable as requested by DSHS NBS Laboratory Managers.

2.2.8 Contractor must deliver testing reagents and consumables according to the following requirement:

A. Deliver testing reagents and consumables only upon request from the DSHS NBS Laboratory Managers in the form of an email. Delivery must be within two business days of specified delivery date;

B. 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 NBS Laboratory personnel and must generally occur on Tuesday between 8:00 a.m. and 1:00 p.m. Central Standard Time;

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

D. Temperature-sensitive testing reagents must be packaged and shipped in a way that must maintain the integrity of the reagents, in accordance to the Contractor's specifications for their products;

E. Use temperature logging sensors to track storage/shipping environment when shipping temperature-sensitive products. Provide logging sensor data within two (2) weeks after DSHS returns the logger;

F. Testing reagents that do not maintain an acceptable temperature storage environment during shipment require replacement at no charge when requested by DSHS NBS Laboratory Managers; and

G. Shipment of incorrect testing reagents and consumables, shipment of incorrect quantity, or inaccurate invoicing must initiate the Assay, Reagent, and Consumable Supply Problem Resolution Steps, as described in Section 2.2.7.

2.2.9 Contractor must provide testing reagents and consumables in quantities according to the following requirements:

A. DSHS reserves the right to increase or decrease annual quantities by fifty percent (50%) with a sixty (60) calendar day notice;

B. Quantity of testing reagents and consumables must allow for testing of three thousand five hundred (3,500) specimens per day, six (6) days per week - plus required calibrators and controls; and

C. Quantity of testing reagents and consumables must be sufficient for daily repeat testing, including calibrators and controls as follows:
    1. GALT: 40 specimens in duplicate
    2. 17-OHP: 100 specimens in duplicate
    3. T4: 300 specimens in duplicate
    4. TSH: 300 specimens in duplicate
    5. IRT: 200 specimens in duplicate
    6. MS/MS: 100 specimens in duplicate
    7. Hemoglobinopathy: 200 specimens in singlicate

2.2.10 Contractor must ensure testing reagents meet the following requirements:

A. The following units of measure will be referenced hereafter.

Unit of Measure	Definition
U/dL	units per deciliter
U/gHb	units per gram of hemoglobin
ng/mL	nanograms per milliliter
µg/dL or mg/dL	micrograms per deciliter
µU/mL	microunits per milliliter
umol/L	micromole per liter

B. Assays must be able to run to completion, from the addition of the first reagent, with a maximum workload completion time as follows:
    1. GALT: 40 microplates within twenty hours
    2. 17-OHP: 40 microplates within nine and one-half hours
    3. T4: 40 microplates within eight hours
    4. TSH: 8 microplates within nine hours
    5. IRT: 40 microplates within seven hours
    6. MS/MS assays must be able to run to completion, from the addition of the first reagent, for 40 microplates within 21-22 hours
    7. Hemoglobinopathy assays must be able to run to completion, from the addition of the first reagent, for 40 microplates within 20 hours

C. Testing reagents must allow for overnight assay completion of 17-OHP, IRT, T4, TSH, GALT, and MS/MS.

D. Supply calibrators and controls with, at a minimum, testing reagents that test for 17-OHP, T4, TSH, IRT, and GALT. Supply calibrators and controls as a single lot number. Provide new lots of calibrators and controls at least one (1) month in advance of usage, to allow for in-house quality control assessment (*which includes establishment of in-house control means and two (2) Standard Deviation (SD) ranges prior to live specimen testing*). A quality control certificate that includes manufacturer means and ranges must be included with each new lot.

E. Supply MS/MS Internal standards and controls with all testing reagents. Supply all internal standards and controls as a single lot number. Provide new lots of internal standards and controls at least one (1) month in advance of usage, to allow for in-house quality control assessment (*which includes establishment of in-house control means and three (3) SD ranges prior to live specimen testing*). Include a quality control certificate that includes manufacturer control means and SDs and internal standard identification and concentrations with each new lot.

F. Final concentration results must be expressed as follows:

   1. U/gHb or U/dL for GALT
   2. ng/mL of serum for 17-OHP
   3. µg/dL of serum for T4
   4. µU/mL of serum for TSH
   5. ng/mL of blood for IRT
   6. umol/L for MS/MS detected analytes

G. Supply blood spot standards (*calibrators*) with each non-MS/MS kit. Supply a minimum of five (5) levels of standards spread throughout the calibration range for quantitative procedures, with minimum concentration ranges as follows:

   1. 1.6 to 18.0 U/gHb or U/dL for GALT
   2. 0 to 200 ng/mL of serum for 17-OHP
   3. 0 to 30 µg/dL of serum for T4
   4. 0 to 500 µU/mL of serum for TSH
   5. 0 to 500 ng/mL of blood for IRT

H. Supply MS/MS internal standards with each MS/MS kit. The Acylcarnitine and amino acid internal standards must include, at a minimum, standards listed below or equivalent:

Table 3

Note: 2H = Deuterium (d)	2H3-Myristoylcarnitine (2H3-C14)
^{2}H9-Carnitine/free carnitine (2H9-C0)	^{2}H3-Palmitoylcarnitine (2H3-C16)
^{2}H3-Acetylcarnitine (2H3-C2)	^{2}H3-Octadecanoylcarnitine (2H3-C18)
^{2}H3-Propionylcarnitine (2H3-C3)	^{2}H4, 13C-Arginine•HCI (2H4, 13C-Arg)
^{2}H3-Butyrylcarnitine (2H3-C4)	^{2}H2-Citrulline (2H2-Cit)
^{2}H9-Isovalerylcarnitine (2H9-C5)	^{2}H3-Leucine (2H3-Leu)
^{2}H6-Glutarylcarnitine (2H6-C5DC)	^{2}H3-Methionine (2H3-Met)
^{2}H3-Hexanoylcarnitine (2H3-C6)	13C6-Phenylalanine (13C6-Phen)

$^2H_4$ ^{13}C-Arginine	$^2H_4$-C26:0-lysophosphatidylcholine
$^2H3$-Octanoylcarnitine (2H3-C8)	$^{13}C6$-Tyrosine (13C6-Tyr)
$^2H3$-Decanoylcarnitine (2H3-C10)	$^2H8$-Valine (2H8-Val)
$^2H3$-Lauroylcarnitine (2H3-C12)	
$^{13}C5$-Succinylacetone (SA) derivative (13C5-MPP) [MPP is 3-(5-methyl-1H-pyrazol-3-yl) propanoic acid]	

I. Provide a minimum of two (2) levels of controls, one (1) in the normal specimen range and one (1) in the abnormal specimen range, with the following exceptions:

1. T4 kit must provide three levels of control (one abnormal low {approximately 2-4 µg/dL}, one borderline, and one normal);
2. 17-OHP kit must provide three levels of control (one normal, one borderline and one abnormal high);
3. IRT kit must provide three levels of controls (one normal, one borderline and one abnormal high);
4. MS/MS kit must contain a low (borderline) and a high (abnormal) control; and
5. Hemoglobinopathy kit must include a control with a minimum, Hb A, F, S, and C.

2.2.11 Contractor must ensure Acceptable Quality Level (AQL) for the analytical testing. Specific assay performance criteria listed below and throughout this Statement of Work must be met. If criteria are not met, Assay, Reagent, and Consumable Supply Problem Resolution Steps, as described in Section 2.2.7, must be followed.

A. T4:
1. DSHS T4 daily mean of initial newborn specimens must fall within thirteen to twenty (13-20) µg/dL. The daily T4 mean value for initial and follow-up screens must not change more than plus or minus ten percent (±10%) at any change of reagent or standards.
2. During new reagent lot evaluations for T4, the evaluated specimen mean concentration must not exceed plus or minus five (±5) µg/dL from the previous lot for normal birth weight newborn specimens.

B. TSH:
1. DSHS TSH monthly positive rate must not change by more than five percent (5%) at any change of testing reagents or standards.
2. During new reagent lot evaluations for TSH, the evaluated specimen mean concentration must not exceed plus or minus ten (±10) µU/mL from the previous lot for normal birth weight newborn specimens.

C. CAH (17-OHP):
1. DSHS CAH daily specimen mean must not change by more than five percent (5%) at any change of testing reagents or standards.

2. During new reagent lot evaluations for CAH, the evaluated specimen mean concentration must not exceed plus or minus fifteen percent (±15%) from the previous lot for normal birth weight newborn specimens.

D. <u>IRT:</u>
1. DSHS IRT daily specimen mean must not change by more than five percent (5%) at any change of testing reagents or standards.
2. During new reagent lot evaluations for IRT, the evaluated specimen mean concentration must not exceed plus or minus ten (± 10) ng/mL from the previous lot for normal birth weight newborn specimens.

E. <u>GALT:</u>
1. DSHS GALT daily specimen mean must not change by more than ten percent (10%) at any change of testing reagents or standards.
2. During new reagent lot evaluations for GALT, the evaluated specimen reporting range must not change by more than one (1) reporting range for more than twenty percent (20%) of the tested specimens.

F. <u>Hemoglobinopathies:</u>

During new reagent lot evaluations for isoelectric focusing, the evaluated specimens and controls must show discrete, focused bands at the expected location.

G. <u>MS/MS:</u>
1. DSHS weekly specimen mean/median for analytes measured by MS/MS must not change by more than five percent (5%) after a kit lot change.
2. During new reagent lot evaluations for MS/MS, the evaluated specimen mean results and CDC results must not change by more than ten percent (10%).

H. <u>New reagent or quality control material lot evaluation:</u>
1. For T4, TSH, CAH and IRT, the in-house established Quality Control (QC) mean must be within twenty percent (20%), or plus or minus two (±2) SD of the Contractor-provided QC certificate stated mean.
2. For GALT, the in-house established QC mean must be within plus or minus two (±2) SD of the Contractor-provided QC certificate stated mean.
3. For MS/MS, the in-house established QC mean must be within plus or minus two (±2) SD of the Contractor-provided QC certificate stated mean.

2.2.12 Contractor must provide assay validation to the extent requested by DSHS for each test that will be newly implemented for the life of this Contract and according to the following requirements:

A. Conduct validation on-site at DSHS NBS Laboratory;

B. Validation must follow the DSHS approved protocol:

1. Validation includes, at a minimum, precision, accuracy, linearity, sensitivity, specificity, split sample and diagnosed case comparisons and cut-off determination. If applicable, includes interferences, limit of detection, and reportable range;

2. Validation includes newborn (N) and follow-up (F) samples, normal, presumptive positive and diagnosed case samples; and

3. Contractor must provide testing reagents and consumables at no additional cost to the State for each validation. New test validations typically include approximately ten to twenty thousand (10,000–20,000) specimens.

C. Contractor must collaborate with DSHS for the validation of each test reagent/kit. DSHS defines kit-specific acceptance criteria prior to initiation of each validation study; and

D. Contractor must work with DSHS staff to provide validation reports, upon completion of validation testing, for DSHS NBS Laboratory Managers, Quality Assurance (QA), and Laboratory Director review and approval. If the validation is unacceptable, Contractor must provide additional testing reagents and consumables at no additional cost to the State (*maximum of two times*) to meet DSHS-defined requirements. If the validation continues to be unacceptable, the reagent/kit will be rejected.

2.2.13 Contractor must provide technical training to DSHS NBS Laboratory staff members for all tests that will be newly implemented or modified for the life of the Contract and as requested by DSHS. Training must be provided according to the following requirements:

A. Provide training onsite at DSHS after installation and receipt of testing reagents and consumables;

B. Provide training manuals;

C. Training must cover all applicable technical aspects of tests, methods and equipment including explanation of test method and theories of methodologies, demonstration of assay, instrument preventative maintenance steps, general troubleshooting steps and general assay review processes. Provide advanced training to technical lead staff identified by DSHS; and

D. Provide training certificate to each DSHS staff member that completes each training.

2.2.14 Contractor must provide ongoing analytical technical support associated with test method for provided testing reagents and associated consumables to include the following:

A. Technical support must include the function of equipment to LIMS interfaces; and

B. Contractor must have a 7:00 a.m. to 4:00 p.m. Central Standard Time technical support hotline Monday through Saturday for all assays and equipment. Contractor

must provide 1-hour response time via telephone or email, including Saturdays. The Contractor must dispatch a local Field Engineer to the DSHS NBS Laboratory to resolved technical support issues not resolved via phone or remote diagnostics. The Field Engineer must contact the DSHS NBS Laboratory within one (1) hour of being dispatched and must arrive on site within eight (8) hours. Contractor must provide a summary report of any service performed within one (1) week of issue resolution.

2.3   Testing Equipment

2.3.1   Contractor must provide the analytical equipment and associated peripheral equipment, including delivery, installation, test, and acceptance (*validation*), service maintenance, upgrading, troubleshooting, and problem resolution, related to testing for the current panel of tests, at a minimum, as described in <u>Section 2.1</u> and within the DSHS-approved timeline. In addition, Contractor must:

A.   Maintain responsibility for all provided equipment and be responsible for all service and repairs required for sustained operation and performance;

B.   Provide redundancy in equipment to ensure continuity of operations if the primary equipment is non-operational;

C.   Supply, install, maintain, and upgrade all computer workstations, software, and peripherals needed to operate the equipment and work in coordination by obtaining approval from DSHS IT and any Third-Party Contractors designated by DSHS;

D.   Ensure complexity of operating procedures must be manageable at the level of CLIA testing requirements for Laboratory staff and training completed within five (5) calendar days;

E.   Provide electronic and/or hardcopy equipment manuals and user manuals;

F.   Provide site preparation guide prior to installation and service/troubleshooting reports;

G.   Provide sufficient analytical equipment and associated peripheral equipment to maintain current throughput, workflow and turnaround time to meet the high DSHS workload, and to fit within the physical location of DSHS NBS Laboratory and any location designated by DSHS;

H.   Provide maintenance to ensure consistent and accurate operation of the equipment;

I.   Provide upgrades, at no extra charge, during the resulting Contract period and any renewals prior to equipment's industry life cycle ending and as software upgrades become available and with DSHS' prior approval;

J.   Provide uninterruptible power supply with a minimum capacity of fifteen (15) minutes coverage, surge and power protection, and power boosting (*if applicable*) to meet manufacturer equipment power specifications; and

K. Ensure accuracy and precision of pipetting volumes must meet manufacturer stated specifications and be acceptable to DSHS for associated test procedures.

2.3.2 Contractor must ensure all equipment provided and installed at the DSHS NBS Laboratory must be capable of the following:

A. Performing daily analysis of estimated three thousand five hundred (3,500) newborn screening specimens per day, six (6) days per week - plus controls and calibrators on each primary screening procedure (*T4, 17-OHP, IRT, GALT, Biotinidase, and MS/MS*) and two thousand five hundred (2,500) retest analyses per day from the combined screen procedures. Quantity of equipment must be sufficient for DSHS staff to reasonably process this workload in an eight-hour workday and be acceptable to DSHS;

B. No more than fifteen (15) minutes of required daily maintenance per system, except for MS/MS equipment, which requires no more than sixty (60) minutes of daily maintenance per system;

C. Equipment used for testing at a minimum GALT, CAH, T4, TSH and IRT must be capable of automated reagent additions, plate transfers, plate washing, and/or disc removal, and automated reading of results must require minimal technician intervention;

D. Equipment, used for testing at minimum GALT, CAH, T4, TSH, IRT, and MS/MS must allow for unattended overnight assay analysis;

E. Operating software must be at a minimum Windows version N/N-1 compatible, and maintained at DSHS required standards;

F. Operating software for all equipment must provide a data repository in case of network downtime and the capability to transfer data once network connectivity is restored; and

G. Operating software for all equipment must provide a data repository of at a minimum thirty (30) calendar days or thirty (30) analytical runs on the equipment's hard drive or an automated back-up system to store at minimum thirty (30) calendar days or thirty (30) analytical runs of equipment data to allow for access and/or re-transmission to the LIMS.

2.3.3 Contractor must provide punching equipment that meets the following requirements:

A. Be provided in a quantity that must be sufficient to allow punching of three thousand five hundred (3,500) newborn screening specimens within four (4) hours for eight (8) primary screening procedures (*T4, 17-OHP, IRT, GALT, Biotinidase, MS/MS, Hb, and SCID*) and up to a total of two thousand five hundred (2,500) retest analyses per day from the combined screen procedures;

B. Be capable of properly handing a sufficient number of plate maps for eight (8) primary screening procedures and associated retest procedures, separate plate maps for placement of calibrators and controls for each screen and retest procedure, and

separate plate maps for PKU monitoring, Hb-HPLC, and second and third tier test procedures;

C. Can accommodate varying numbers of specimens in the plate maps for the primary screen procedures and automatically stop punching when specimen wells on any assay plate are completely filled. Contractor must supply sufficient additional punching equipment (*type of equipment must be acceptable to DSHS*) for separate sample placement of calibrators and controls on screen plates and for punching the retest assays;

D. Be capable of punching spots sized appropriately for the testing performed at DSHS to include at a minimum, 3.2mm (1/8") spots, 4.7mm (3/16") spots and any other size required by testing reagents provided as part of this Contract;

E. Require no more than fifteen (15) minutes for daily setup of each machine;

F. Include barcode to positively identify assay and specimen group for all plates being processed. Punching equipment must positively identify the specimen using the barcode specimen number and capable of interfacing to a LIMS. Punching equipment must be upgradeable and compatible with future versions of LIMS software and Windows;

G. Be capable of punching a minimum of six (6) 3.2mm (1/8") test spots per specimen blood circle simultaneously;

H. Be capable to punching four (4) to six (6) 3.2mm (1/8") test spots per calibrator (*standard*) or control blood circle simultaneously;

I. Include a system to verify disc placement in sample well such as a disc detection system or a disc guide to ensure correct placement;

J. Include a guide for positioning the blood sample and the ability for the operator to pause the program for punching a smaller number of samples from multiple circles, when required, followed by an automatic resumption of the routine program; and

K. Be capable of punching specimens off-line without a network connection and without requiring a barcode.

2.3.4 Contractor must provide T4, TSH, 17-OHP, IRT, and GALT equipment that meets the following requirements:

A. Capable of running all analytes on the same equipment;

B. Fully automated and performs all assay steps without technician intervention;

C. Capable of unattended operation for overnight analysis of specimens and have the capability to load at least twelve (12) plates for unattended analysis;

D. Include sufficient power back-up to provide protection during a power surge or for the switch from regular to emergency power during a power failure;

E. Capable of tracking assay and plate numbers through barcode identification;

F. Include a system that must monitor and log all steps of run to ensure accurate and precise liquid delivery;

G. Include on-board controls to monitor and regulate temperature and environmental factors to eliminate edge effect in microplate assays;

H. Capable of automatically checking for adequate supplies of testing reagents and consumables prior to run initiation and send notification when supplies and consumables are not adequate; and

I. Include a system that must automatically schedule all assay processing steps after sample loading with an operator override for user defined scheduling of assays.

2.3.5 Contractor must provide Biotinidase equipment that meets the following requirements:

A. The liquid handling systems used must be capable of precise reagent addition at volumes between twenty-five to five hundred (25-500) microliters with an accuracy and precision less than or equal to two percent (2.0%) by the methodology used for up to twenty-four (24) microtiter plates and must be programmable to conform to end user needs to the satisfaction of DSHS; and

B. Incubation units must have a programmable capability that includes accurate and precise temperature control encompassing the test temperature range of thirty-five to thirty-nine degrees Celsius (35-39°C), the length of the incubation cycle of six (6) hours and sustainable agitation speeds of eight hundred fifty to nine hundred fifty (850-950) rotations per minute for the methodology used.

2.3.6 Contractor must provide MS/MS equipment and user licensed copies of the MS/MS equipment operating and data processing software. Contractor must provide four (4) additional licensed copies to DSHS to perform MS/MS testing review, at separate workstations. MS/MS equipment and software must meet the following requirements:

A. Equipment must be fully automated and perform sample analysis steps with technician intervention required only at initial start of sample analysis. MS/MS equipment must be capable of unattended operation for overnight analysis of specimens and must include the capability to load at least twelve (12) plates per equipment for unattended analysis;

B. Software must allow for sample analysis to begin at a predetermined/scheduled time without user intervention except for assay start scheduling;

C. Equipment must have sufficient power back-up to provide protection during power surges and/or during the switch from regular to emergency power during a power failure;

D. Systems must monitor and log the reason for equipment shutdown and the type of error associated with shutdown and/or that proper shutdown occurred;

E. Incubation units must have a programmable capability that includes accurate and precise temperature control encompassing the temperature range, length of the incubation cycle, and sustainable agitation speeds (*if necessary*) for the methodology used; and

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F. Operators must be able to override MS/MS assay analysis steps after initial startup as needed.

2.3.7 Contractor must provide equipment validation for provided and installed equipment and for newly implemented equipment during the Contract term and any Contract renewals. Contractor must provide validation at DSHS' request and conduct validation on-site at the DSHS NBS Laboratory as follows:

A. Validation must follow the level of CLIA testing requirements. The link to these requirements are listed in Section 2.2.5;

B. Validation includes, at a minimum, precision, accuracy, linearity, sensitivity, specificity, verification of the reportable range, carryover, equipment comparison, split sample and diagnosed case comparisons, and cut-off determination;

C. Validation includes newborn (N) and follow-up (F) samples, normal, presumptive positive, and diagnosed case samples;

D. Contractor must provide validation testing reagents and consumables at no additional cost for each validation. New equipment validations typically include an estimated five hundred to two thousand (500–2,000) specimens per equipment;

E. Contractor must conduct validation in cooperation with DSHS staff members;

F. DSHS will develop equipment-specific acceptance criteria for equipment to be provided by the Contractor prior to the initiation of an equipment validation study; and

G. Contractor must work with DSHS staff to provide validation reports, upon completion of validation testing, for review and approval by DSHS NBS Laboratory Managers, QA, and Laboratory Director. If after review of these reports by DSHS, validation is unacceptable, Contractor must provide additional testing reagents and consumables at no additional cost to the State (*maximum of two times*) to meet DSHS defined requirements. DSHS will reject testing equipment, if the validation continues to be unacceptable.

2.3.8 Contractor must provide training and training materials, if available, for all testing equipment that will be newly implemented for the Contract term and any renewals as requested by DSHS. Contractor must provide training according to the following requirements:

A. Contractor must provide training onsite within seven (7) calendar days after installation and receipt of testing reagents, and consumables;

B. Contractor must provide training manuals;

C. Training must cover all applicable technical aspects of tests, methods and equipment including explanation of test method and theories of methodologies, demonstration of assay, instrument preventative maintenance steps, general troubleshooting steps and general assay review processes. As appropriate, advanced training must be provided to technical lead staff identified by DSHS and within seven (7) calendar days of request; and

D. Contractor must provide training certificate to each DSHS staff member that completes each training.

2.3.9 Contractor must provide equipment maintenance and support that meets the following requirements:

A. Contractor must provide four (4) full-time field service personnel to provide routine maintenance and troubleshooting support for testing equipment and systems, Monday through Saturday, 8:00 a.m. to 5:00 p.m. Central Standard Time at the DSHS NBS Laboratory;

B. Contractor must perform analytical equipment maintenance to meet or exceed the requirements listed in the manufacturer's instruction manual. Contractor must schedule analytical equipment maintenance in advance with the specific DSHS NBS Laboratory Managers that is responsible for the equipment to minimize impact on testing workflows and reporting timelines. Contractor must provide a detailed report of any maintenance performed, including a list of maintenance work completed and data obtained during parameter checks, within one (1) week of completion to DSHS NBS Laboratory Managers. Contractor must provide routine MS/MS equipment maintenance at a minimum four (4) times a year;

C. Provide equipment optimization and normalization to ensure all equipment (*across a specific test*) are well matched and do not require different abnormal cutoffs for each individual equipment;

D. Field support staff must maintain a reasonable amount of replacement parts for equipment with known and frequent breakdowns;

E. Contractor must provide service parts at no additional charge to maintain provided test systems;

F. Contractor must provide service for DSHS-owned Migele Gel Electrophoresis Units, including service reports;

G. Contractor must perform all service on analytical laboratory equipment systems. Contractor must have a 7:00 a.m. to 5:00 p.m. Central Standard Time hotline support Monday through Saturday for the equipment systems. For analytical laboratory equipment, Contractor must provide 1-hour response time via telephone or e-mail and an 8-business-hour on-site response time, Monday through Saturday, when remote service cannot resolve the issue. Contractor must provide a summary report of any service performed within one (1) week of issue resolution; and

H. Provide equipment upgrades at no additional cost to the State as technically appropriate and approved by DSHS to maintain optimum performance, including upgrade equipment due to age or incompatibly with new operating or security systems.

2.3.10 Contractor must utilize the Equipment Problem Resolution Steps to include the following:

A. DSHS will immediately notify the Contractor by telephone, email or in person. When contact is made in person or telephone, DSHS staff will follow-up with an e-mail or in writing to document initiation of request;

B. Upon notification of a problem, Contractor must initiate troubleshooting by either remote support or field engineer and provide routine status updates until resolved;

C. Contractor must provide documentation of any remote troubleshooting or field service provided resulting in equipment adjustments within one (1) week of issue resolution;

D. Contractor must replace equipment with unresolved problems within an agreed upon time-frame with DSHS, so the testing is not disrupted; and

E. Obvious or chronic equipment failure resulting in reagent, consumable supply, or specimen loss must result in timely reagent, consumable supply, kit, or equipment replacement at no cost to DSHS following request by a DSHS NBS Laboratory Managers.

2.3.11 Contractor must provide and maintain bi-directional interfaces between equipment and LIMS on equipment owned by DSHS and equipment provided by the Contractor.

2.4 Laboratory Information Management System (LIMS)

2.4.1 Contractor must provide LIMS that meets the following requirements:

A. The software and workstations components on which the LIMS operates must all be commercially available and must comply with DSHS infrastructure and architecture standards. (*This includes client and server platforms, network components, database management systems, query tools, and programming languages*).

B. The LIMS must operate within that infrastructure as an application, co-existing with other applications.

C. No part of the environment must be proprietary to the LIMS Contractor except the LIMS source code itself.

D. Contractor must disclose the application's data model to DSHS and provide full data base administrator and developer access to the database.

E. The software must provide import and export data functions. For example, the LIMS must allow DSHS IT personnel to update all records to accommodate a mandated change in the Texas Provider Identification for Medicaid.

F. Document management, record management, and/or character recognition capability seamlessly integrates with any existing agency-wide Enterprise Content Management solution.

2.4.2 Contractor must comply with the following DSHS security and control requirement:

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A. Contractor must comply with agency policies regarding building access and physical security as appropriate. The Contractor must conform to the State of Texas Security policies and procedures for handling data. Contractor must not use, sell or share personally identifiable or private information collected for any purpose other than the intended purpose. In the event of a security breach or disclosure of protected health information or personally identifiable information, Contractor must be responsible for notifying anyone affected by such a security breach. Failure to comply with security standards may lead to the suspension or termination of this Contract. If a security breach occurs on the DSHS's side, the Contractor must not be liable if the agency is at fault.

B. Contractor must require all Contractor staff working with the DSHS Contract and with access to confidential information to sign the DSHS security and confidentially forms which state that all personnel must abide by the DSHS security and confidentiality policies and procedures as related to IT security. The forms include: "Health and Human Services Enterprise Computer Use Agreement" and "DSHS Confidentiality and Non-Disclosure Agreement". Copies of the form(s) are available upon request. In addition, all Contractor staff working with the DSHS Contract must be required to complete a DIR certified cybersecurity training program. This includes Officers, employee, and Subcontractors of the Contractor.

C. Contractor must require all Contractor staff working with the DSHS Contract and with access to confidential information complete a DIR certified cybersecurity training whether staff are on-site at DSHS or off-site.

D. Contractor must ensure the LIMS meets the following security and control requirements:
   1. Mechanisms must be in place to ensure integrity of data, including deletion or corruption of the data by the application.
   2. Prevention of unauthorized access to the system via: use of strong passwords, password expiration, and logoff after a specified period of no use.
   3. Alert messages when system errors requiring staff intervention occur.
   4. Backup, event logging, and recovery procedures for system recovery and root cause analysis.
   5. An access control function that allows a security administrator to establish and update each user's level of access to individual application functions and to categories of data.
   6. The LIMS application must enable the laboratory to be compliant with the Health Insurance Portability and Accountability Act (HIPAA) and all Texas laws and regulations that govern confidentiality of patient confidential information.

2.4.3   Contractor must comply with the Support Change Management Process according to the following requirements:

A. No production server operating system or software patching, application changes or maintenance can occur without written approval from the Change Management Board.

B. No production server infrastructure changes or maintenance can occur without approval in writing from the Change Management Board.

C. Submit needed changes to the Change Management Board using the approved IT change request form. DSHS will provide the IT change request form upon execution of the Contract.

D. Meet with the Change Management Board at the request of DSHS.

E. All changes require a unanimous vote from all Change Management Board members or their assigned proxy.

F. Change Management Board members are one (1) representative from each of DSHS IT Application Development, DSHS IT Operations, DSHS Lab and the Contractor.

G. This process must not affect the test or development environment.

2.4.4 Data Migration: In the event the next RFP results in a LIMS different than the one currently in use, Contractor must coordinate with the incumbent Contractor to migrate all active and archived data from the current system into the new LIMS or LIMS upgrades.

2.4.5 Contractor must ensure LIMS performance must effectively accommodate the various laboratory characteristics as they interact in required ways throughout the laboratory screening and clinical care coordination operations. The laboratory requires LIMS to be compliant with Electronic and Information Resources Accessibility and Security Standards as described in Attachment E, HHS Additional Provisions and to have the following functions:

A. Testing Volume: The LIMS must provide high volume processing, providing a high level of automation of data entry and workflow while providing easy access to information for monitoring and controlling the process and handling exceptions. Staff involvement needs to be intuitive and logical, minimizing the time and effort required to perform functions, monitor processes, and interpret information presented by the LIMS. Further, the LIMS needs to be scalable to grow as volumes increase.

B. Unique handling for each disorder: LIMS must allow tailoring laboratory operations, analytical processes and methods for each disorder to properly conduct tests, analyze results, and follow-up on abnormal results. LIMS must also be able to accommodate tests for additional disorders, new methods and new technologies over time.

C. Accuracy: LIMS must be able to ensure test results are valid and are associated with the correct specimen for the right patient. In addition, LIMS must allow laboratory staff the ability to detect and correct data errors and functions performed

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in error and to be able to trace activities to determine where a previously undetected error occurred.

D. Capacity: LIMS must be able to maintain demographic and testing data for all specimens in an active production environment for a period of at least two (2) years. LIMS must provide the ability and capacity to scan and store images of newborn screening specimen demographic information sheets in a format that is easily accessible. Future LIMS product must archived for a minimum of nineteen (19) additional years (*following the DSHS retention schedule requirements*). Archived data must be easily accessible to all authorized users.

E. Intensive Inquiry: The LIMS must provide interactive and customizable queries, standardized reports, and ad-hoc reports to enable DSHS NBS Laboratory and DSHS Clinical Care Coordination staff to rapidly and effectively obtain information from the system.

F. New Testing Technologies: The LIMS must be expandable to accommodate new technologies.

G. Out-of-State Specimens: The LIMS must include functions that allows DSHS to test out-of-state specimens while maintaining the capability of excluding or including these specimens for the following:
1. Calculating testing cut off values;
2. Compiling statistical reports; and
3. Creating clinical care coordination cases.

2.4.6 Contractor must provide LIMS with the following:

A. A single enterprise license agreement must cover DSHS (*and any successor agency*) and its facilities such as contractors, external stakeholders, and clinics utilizing the software. The enterprise license agreement is a non-exclusive, fully paid, lifetime license (*with no recurring charges for licensing*). The license fee must include all upgrades and configuration needed for the upgrades for the period of the Contract.

B. Documentation of the following items:
1. List of modules included with the system;
2. List of tables and database structures accessed or modified by each table;
3. Complete database dictionary of the installed system at DSHS including data element names with the description and purpose and the database keys; and
4. Business process and data workflow diagrams of the final system installed at DSHS and upon completion of any system changes implemented throughout the Contract term and any renewals. Each drawing(s) must match each business and system function to the database tables and show any changes applied to the database tables during the progression through the business process.

2.4.7 **Specimen Collection Kit Management Module** - Contractor must provide a specimen collection kit management module capable of managing the following functions:

A. <u>Order Processing:</u> For managing orders of specimen collection kits, the module must provide and support the following:

1. Entry and fulfillment of orders for newborn screening supplies (*specimen collection kits, envelopes, labels*) received from submitters of newborn screening specimens, including documentation of the quantity and range of cards issued along with the quantity of envelopes and labels;
2. Business variants such as partial shipments, alternative shipping methods, back orders, different delivery addresses and notes specific to each order or submitter;
3. Business exceptions such as error correction, un-shipping, return of ordered items prior to shipment, and orders placed on hold;
4. Maintain detailed shipping records including quantities, and specific form serial numbers shipped;
5. Barcode scanning entry and keyboard entry of the form serial number to facilitate order processing;
6. View the submitter history from the kit order window/function;
7. Edit the date range to adjust the search time-period in the submitter history query;
8. Data entry capabilities to enter specimen collection kit orders received from newborn screening submitters representing many different locations of the same organization;
9. Run reports of specimen collection kits shipped for billing any entities such as the submitter or Medicaid;
10. Run reports of unused, remaining specimen collection kits for each submitter;
11. Print shipping labels from any DSHS network printers;
12. Print shipping labels for the same submitter at different addresses; and
13. Print barcode labels from independent barcode printers.

B. <u>Order Returns:</u> For managing returns of specimen collection kits, the module must provide and support the following functions:

1. Record receipt of unused/blank NBS collection forms returned from submitters for a credit or other reason;
2. Run a report of specimen collection kits returned for use in processing a credit to the submitter or to update the record for billing purposes; and
3. Return NBS collection forms and reissue returned forms to submitters.

C. <u>Inventory Management:</u> For managing the inventory of specimen collection kits, the module must provide and support the following functions:

1. Manage inventory of supplies, including inventory of specimen collection kits by individual form serial number, type, and/or expiration date;
2. Manage specimen collection kits that are approaching or have passed their expiration dates;
3. Enter NBS specimen collection device inventory into the LIMS, sort into different categories (*such as Current Inventory, All Removed Cards, Damaged*

Cards, Returned, Hold, Other) and validate data entry to trigger alert when form serial number range is incorrectly entered;

4. Enter newly received inventory into the system;
5. Enter new form serial numbers each year including expiration dates and assignment as to type of form (*such as Medicaid, Paid, Other*);
6. Make corrections to date of expiration and range of specimens moved into active inventory module; and
7. Alerts and notification of possible input errors.

D. <u>Submitter Management</u>: For managing the inventory of specimen collection kits, the module must provide and support the following functions:

1. Maintain complete, up to date records of each submitter;
2. Enter, edit, update, inactivate, and delete submitter location and contact information, including those submitters and contacts representing multiple facilities;
3. Track submitter information changes;
4. Maintain a record of contacts with submitters; and
5. Search for a submitter with query results to include information as to billing hold status.

E. <u>General Kit Management Functions</u>: In future LIMS product, the module must provide the following functions:

1. Archive kit management specific data; and
2. Audit any changes to a record.

2.4.8 Specimen Receiving Module - Contractor must provide a specimen receiving module capable of managing the following functions:

A. <u>Specimen Receipt</u>: Record specimen receipt by scanning the form serial number into LIMS. This will apply the received date and time on the existing record associated with that form serial number.

B. <u>Laboratory Specimen Identification (ID) Number Assignment</u>: For ID number assignment, the module must provide the following abilities:

1. Scan barcodes on specimen collection kits to assign the appropriate specimen ID number;
2. LIMS assigns the next sequential specimen ID number in the range specified by the user to the record;
3. Assign specimen type or category (*such as; Newborn, Follow-up, Internal Control, Global Unsatisfactory, Out of State specimens, or Proficiency Test*);
4. Assign unsatisfactory codes to global unsatisfactory specimens;
5. Identify and flag specimens, by the form serial numbers, that have not been date received or assigned a specimen ID number and placing them on a priority list. This must notify the user when the form serial number scans into the LIMS;
6. Maintain an audit trail for specimens placed and removed from priority list;

7. Edit, change, or correct steps of processed specimens when necessary (such as; changing date of receipt, changing specimen type, deleting and re-assigning specimen ID numbers);

8. Print replacement barcodes for damaged or changed form serial numbers;

9. For specific functions, provide controls to limit access (*such as changes to passwords*);

10. Update system to allow receipt of specimens with form serial numbers that have an updated year; and

11. Change the specimen ID format when needed for workflow or process improvements approved by DSHS for implementation.

2.4.9 Submitter Maintenance Module - Contractor must provide a submitter maintenance module capable of managing the following functions:

A. Storing, updating, creating, retrieving and exploring submitter information; allowing generation of reports and sorting by submitter number, agency/facility, NPI number (to be included on future LIMS product), name, address, city, state, zip, phone/fax numbers, email and the method for receiving result report (*mail, fax, HL7*). *E-mail and/or secure web application* to be included on future LIMS product for method of receiving result report; and

B. Maintain multiple addresses and contact numbers for each facility (*such as ones for result report delivery, kit order delivery, bill and invoice delivery, contact number for laboratory, nursery, NICU, and NBS coordinator*).

2.4.10 Demographic Entry Module - Contractor must provide a demographic entry module capable of managing the following functions:

A. Demographic Entry: For demographic entry, LIMS must provide the ability:

1. To scan or keyboard enter the form serial numbers to initiate data entry;

2. Upon scanning or entering the form serial number, the specimen number and submitter information from the Kit Management Module must be automatically populated into the demographic entry screen. Ability to enter or overwrite this information if it has not previously been recorded or does not match the information on the form;

3. The demographic entry screen matches the demographic form of the NBS collection kit to facilitate rapid data entry;

4. The demographic entry screen is modifiable as needed to reflect changes to the specimen demographic form;

5. Future LIMS product must have the ability for the demographic entry screen options to automatically adjust to accommodate different data entry options for different form serial number ranges;

6. Supply field defaults, where appropriate;

7. Demographic entry processes must have no delays and no mouse dependencies;

8. Perform validity checks when entering data, where appropriate; and

9. Upon scanning or entering the form serial number or barcode, import demographic information received through HL7 interfacing or import of data from third-party remote data entry via web application.

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  a. Remote entry import must provide the ability to filter out non-required fields that do not meet data format or validation requirements.

 B. <u>Verification</u>: For verification, the module must provide the following functions:

  1. Ability to verify and correct re-displayed or printed data;

  2. Ability to automatically compare critical fields such as; date of birth, date of collection, and birth weight, and the ability to enter the information again if it is found to be incorrect;

  3. Maintain an audit trail of all modified information. Ability to replace data within individual fields without having to delete the individual record;

  4. Maintain an activity log to record individual updates after verification; and

  5. Scan, store, and associate images of the demographic form and other documents with appropriate specimen records.

2.4.11 Matching and Linking Module **-** Contractor must provide a matching and linking module capable of managing the following functions:

Table 4

Baby's DOB	Zip Code
Baby's Last Name	Phone Number (excluding invalid numbers)
Mother's First Name (first 4 letters)	Father's Last Name
Mother's Last Name	Medicaid Number
Mother's Maiden Name	Previous Serial Number
Mother's DOB	Medical Record Number
Mother's SSN (excluding invalid numbers)	Physician's Name
Street Address (first 7 digits/letters)	Physician's Phone

 A. Compare linked specimen records for a number of criteria (*e.g., the mother's name and social security number and the child's date of birth*);

 B. Identify potential automatic linked and non-linked specimen records for DSHS staff review and matching;

 C. Allow manual linking and un-linking of specimen records independent of the automatic linking process;

 D. Identify potential manual linked specimen records for DSHS staff review and final determination;

 E. Schedule matching and linking processes to run automatically in a way that it does not interfere with demographic entry for subsequent specimens or system performance; and

 F. Link matching specimens immediately when identified, but potential matching specimens must be retained for DSHS staff review.

2.4.12 Contractor must ensure DSHS owned equipment and analytical equipment provided by Contractor interfaces with the LIMS application. Prior to implementation, the Contractor must provide an interface solution to DSHS for approval.

A. Punching must:

1. Use DSHS designed punching patterns (plate maps) for each type of microtiter test plate (*including disorder type and microtiter plate purpose, such as screen, retest, and custom*) using DSHS owned, BSD300 punching instrument and Contractor provided punching equipment;
2. Scan plates and specimens to positively identify the location of each specimen on each plate;
3. Verify completion of accessioning of specimens;
4. Provide alerts if specimens are not scanned in order;
5. Complete re-punches and tracks re-punched specimens; and
6. Provide ability to allow exceptions to the normal punching routine. Specimen plates are not always punched at the same time. (*e.g. punch Hb, MSMS, SCID and BIOT first, punch T4, CAH, IRT, and GALT late*r).

B. General screening functions must:

1. Provide positive identification feature to track each specimen from receipt to report;
2. Handle each analyte separately, only deal with one (1) analyte or specified combination of analytes on the screen at one time (*e.g. if working with CAH only want to see information dealing with CAH, or if working with MSMS only want to see information dealing with MSMS, possible combinations include T4 with TSH*);
3. Allow manual entry of result data. For example, the Hemoglobinopathy and biotinidase deficiency screening process consists of manual entry of result data at some steps of the process;
4. Function in one section of the laboratory and does not interfere with functions in other sections of the laboratory (*i.e.: merging of analytical data in CAH does not interfere with processes taking place in MSMS*);
5. Default all specimens to normal prior to work list use in determining the final result code. The default to normal results must occur automatically for all tests rather than requiring the analytical areas to default their results to normal. CAH has two normal codes that are birth weight dependent. Thyroid screening has two normal codes associated with T4 only analyzed or T4 and TSH both analyzed;
6. Handle complete or partially failed assays by creating re-punch assays, which is a user specified group of specimens that must be completely reprocessed in the analytical laboratory due to a process failure for one, several or all analytes. All process steps must include punching, analysis, QC acceptability, data merged into LIMS and data review. Re-punch data merged into the LIMS may include data from other assays with different dates;
7. Perform actions on a range of laboratory numbers rather than requiring them for each laboratory number individually;

8. Have the ability to enter notes for each specimen;
9. Provide result code calculations and final worklist review and release of specimen results;

   a. Perform the statistical calculations and assigns the final test result code that are different for each analyte and dependent on the specimen demographic information;

   b. Ability to enter free text results;

   c. Ability to enter same result for a group or range of specimens; and

   d. Use DSHS current result code listing to assign final result; see http://www.dshs.state.tx.us/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=8589977621.

10. Create analyte specific worklists using the pull list. The worklists include fields specified by the individual assay section, to include but not limited to the screen result, all retest results, appropriate demographic information, the averaged result (*per DSHS protocol*), CV and LIMS calculated result code;
11. Flag records if multiple births or changes are made to birth weight;
12. Create DNA worklists that contains specimens that met DSHS defined criteria;
13. Provide the flexibility to fix, edit, modify, and adjust data/information such as final result codes, batch sizes, and specific specimens included in a batch;
14. Provide an unsatisfactory result for individual disorders;
15. Manage specimens and assays from multiple dates that are at various stages of the analysis process;
16. Release results by various groupings, such as Normal, Abnormal, Date, individual specimen number, or specimen number range; and
17. Put processing on hold if demographic data is required for the process and demographic entry and verification is not complete.

C. Equipment Interface must:

   1. Provide bi-directional equipment interfaces for analytical data to transfer into the LIMS, and to include, but not limited to, worklists, method files, and specimen category to be transferred to the analytical equipment;

      a. Create analytical batches (*screen, retest, re-punch, other*) to be sent to the analytical equipment to ensure the equipment analyzes specimens. DSHS will specify analytical batch specifications; and

      b. Capture result data files (*screen, retest, re-punch, other*) from the analytical equipment when specimen analysis is complete.

   2. Solution must be scalable to allow for the addition of equipment; and

   3. Provide all quantitative laboratory results, through an automated system in real time, for data and statistical review and assessment of results;

      a. Capture and retain all analytical values for a specimen (screen, all retest values, final result averaged value); and

      b.   Create pull lists (*repeats*) of specimens that meet the repeat criteria. DSHS will specify repeat criteria that are not the same for different analytes.

D. Analyte and Disorder flagging (*Calculations*) must:

1. Have the ability to use of age and infant weight-based analyte cutoffs;
2. Flag the results in categories such as normal, borderline, moderate, elevated, or decreased for each individual analyte and disorder;
3. Configure age-based cutoffs for multiple age ranges such as below one (1) week, above one (1) week, and unknown;
4. Associate each disorder with a fixed (*static*) group of analytes;
5. Provide for different primary and retest screen configurations. Options include manual entry or result downloads from the appropriate equipment;
6. Provide for reflex test algorithm to forward specimens meeting DSHS guidelines for additional testing and must allow users to add and remove specimens for additional testing;
7. Allow for DSHS to approve disorder algorithms, result reporting descriptions, and result codes; and
8. Allow for the final result releasing function to be manually triggered following a second analytical review of final data determination.

E. Analytical Laboratory QA/QC must:

1. Track QC and assay parameters such as specimen mean, standard deviation data by user-defined parameters including various date ranges, equipment combinations, and analyte levels;
2. Have the ability to calculate QA parameters such as control means, standard deviation values, and number of points included;
3. Provide on-screen and hard copy option of Levy-Jennings charts and data text formatted reports;
4. Provide control points to be disabled if it meets user defined criteria. Disabled points are not included in calculation of QA parameters and must be available for viewing; and
5. Create and maintain information about each kit lot used for each assay. Maintain reagent kit lot numbers, expiration dates, and calibrator concentrations.

F. DSHS Clinical Care Coordination notification must:

1. Send real-time notification of abnormal test results to DSHS Clinical Care Coordination staff for follow-up case creation and processing in the follow-up module; and
2. Have the ability to notify DSHS Clinical Care Coordination staff immediately upon the release of a "panic" value result that requires immediate action.

G. Result Reports, known as "Mailers" must:

1. Create a result report automatically only upon release of all associated demographic information and all analytical test results;

2. Create a result report for all specimens designated as global unsatisfactory automatically only upon release of all associated demographic information;
3. Electronically retain a created image of a report to meet accessibility and retention requirements;
4. Create separate result generation runs for physical prints and other reporting formats;
5. Create a unique report number for reports generated on a given day;
6. Create a final result report that must be sent by automatic faxing, hard copy printing, email, or HL7 message to the specimen submitter. LIMS must categorize the method in which the report was sent for easy retrievable through a query;
7. Make PDF result reports available for retrieval through existing third-party secure web application;
8. Have the ability to turn off hard copy printing for submitters that select other methods of result reporting;
9. Have the ability to reprint multiple duplicate or revised reports as needed in batches or individually;
10. Ensure duplicate results reports are an exact copy of the most recently generated result report. Future LIMS product must electronically track the date and time of printing of each duplicate;
11. Include in revised result reports all previously reported results for the given specimen;
12. Include in the result report the items in Table 5;

Table 5

Submitting facility name and address	Patient's gender
Submitting facility identification (ID) number	Patient's birth order
Patient name: Last, First	Specimen screen category (*Less than seven days old, seven days or older, previous abnormal*)
Laboratory number	Feeding type (*i.e.: Breastmilk only, formula only, TPN + milk, Breastmilk & Formula*)
Form serial number	Status (*i.e.: normal, sick/premature, on medications, transfused*)
Patient's date of birth	Physician name
Date of specimen collection	Physician telephone number, including area code
Date of specimen receipt in the laboratory	List of disorders tested
Date of original specimen result report	Overall result status of specimen
Date of revised specimen result report (*if applicable*)	Result (*or unsatisfactory status*) for each disorder
Print Date of Report	Analytes and analyte results used to determine out of range results
Mother's name: Last, First	Screening Result Notes to accompany each non-normal result
Mother's address, including city, state and zip	Optional area to insert informational banner messages on all reports

Mother's telephone number, including area code	Area to insert mailer reprint reason (*e.g. duplicate report, revised report*)
Patient's medical record number	Area for notation of remotely entered demographic information
Patient's birth weight (*in grams*)	Area for DSHS disclaimer statement
Patient's race/ethnicity	Areas for any internally developed testing methodologies.

13. Provide ability for a list for up to three (3) unsatisfactory reasons for global unsatisfactory specimens;

14. Provide a solution for transmitting results through HL7 to facilities that have submitted HL7 test orders;

15. Ensure the result report format must be:

   a. Configured to print on DSHS provided printer;

   b. Designed for mail machine equipment to separate reports by submitter;

   c. Formatted to print abnormal (*out of range*) reports before normal reports;

   d. Formatted to separate the DSHS specified number of reports into one (1) envelope for the same submitter;

   e. Designed to allow for multiple page mailers;

   f. Printed on "plain" paper and must include a DSHS specified headers, including logo and laboratory contact information; and

   g. Including a specimen information section to display information from the demographic information form;

16. Ensure the Display Results Section must include:

   a. Provide ability to group disorder results;

   b. Groups with no out-of-range disorders with a result indicating all analytes are within range;

   c. Groups with out of range disorders with only the analytes and analyte results used to determine results for the out of range disorder;

   d. Analytes for an out of range disorder must always display whether the individual analyte is elevated. Other elevated analytes or secondary ratios not tied to this disorder must not display;

   e. Analytes are displayed only once within each disorder group;

   f. CF-DNA reflex testing results to merge into result report;

   g. Display of result notes section with a result note for each out of range result;

   h. Display of comments section with an editable field for global comments. Provide ability to print comments mailers printed at the same time; and

   i. Display of footer sections as specified by DSHS which may include page and date information, list of all disorders tested, laboratory disclaimer, reference range, and internally developed methodology statements;

17. Ensure the Result Report Print Order must sort in the following order:

       a.   Initial - out of range specimens and normal specimens;

       b.   Secondary - zip code; and

       c.   Tertiary - submitter or provider; and

18. Have the ability to print separate result reports required for PKU Monitoring and the DNA second-tier tests. See additional information about second-tier testing in <u>Section 2.4.14 (C).</u>

2.4.13 DSHS Clinical Care Coordination – Newborn Screening Follow-up

A. Contractor must provide LIMS functions to support clinical care coordination Case Setup, Assignment, and Viewing to include the following:

1. Upon release of the first abnormal rest results of a newborn, create a clinical care coordination case and assign it to DSHS Clinical Care Coordination staff (*if clinical intervention is required*) and associate the appropriate workflow to the case;

2. Execute these functions based on configuration tables, managed by DSHS Lab staff that identifies the DSHS Clinical Care Coordination staff, establishes the assignment criteria, defines the workflows, and the secondary and long-term workflow triggers;

3. Link each case with viewing access to all testing records and patient demographic information upon release of NBS results;

4. Allow DSHS Clinical Care Coordination staff to see the list of cases assigned to them, as well as the list of cases assigned to other DSHS Clinical Care Coordination staff;

5. Upon release of new screening results for an open case, notify DSHS Clinical Care Coordinator staff;

6. LIMS must support case setup and assignment under the following situations:

       a.   For multiple abnormal test results for the same specimen, provide the ability to release test results for each different screening tests independently. When a case has been set up and casework has begun, provide the ability to assign the new abnormal result to a second DSHS Clinical Care Coordination staff based on the results of the second test. Provide the ability for two (2) DSHS Clinical Care Coordination staff working the same case to recording follow-up activities in the same set of notes; and

       b.   Provide the ability to manually setup a case to accommodate special situations such as, when an abnormal test result comes from an out-of-state laboratory for a patient who resides in Texas.

7. LIMS must provide an electronic record for each newborn that requires follow-up to include:

       a.   Recommended follow-up actions (*based on specified DSHS protocols*) for the screening results and confirmatory test results;

      b.   Documentation (*notes field*) of telephone, written, and fax contacts with medical personnel and family;

      c.   Contribution to case notes (*for example, updating baby's name by a case coordinator on a specific date*);

      d.   Documentation of work activities including, dates and times and notes entered/updated;

      e.   Documentation of DSHS Clinical Care Coordination staff completing workflow actions and entering notes;

      f.   Viewing access for information associated to the newborn, including health care providers by type (*PCP, specialist groups*), original and updated demographic data, lab screening results, diagnosis, closure code/reason, treatment and comments;

      g.   A process to store and associate with patient, all scanned diagnostic test results and other documents received from outside laboratories; and

      h.   Search criteria by original or edited demographic information.

B. Contractor must provide LIMS functions to support clinical care coordination workflow. Each disorder must have a similar workflow to include the following features of the six basic types of steps:

1. Making contacts - The workflow identifies the contacts DSHS Clinical Care Coordination staff need to make for this case and may offer decision trees based on variables such as disorder, weight, or gender;

2. Sending letters to providers and parents. The DSHS Clinical Care Coordination staff sends a letter outlining the initial actions providers must take in response to the abnormal results;

3. Documenting the category of person notified, such as submitter, PCP, parent, and time of notification;

4. Requesting follow-up test results - The workflow identifies the follow-up tests to be performed and sets reminders for results until received;

5. Requests diagnosis or clearing baby of certain diagnoses; and

6. Moving case into Long Term Follow-up flow if indicated.

C. Contractor must provide LIMS functions to support clinical care coordination casework to include the following:

1. Provide steps in the workflow to the DSHS Clinical Care Coordination staff in succession, tracks progress through the workflows, triggers and tracks secondary, and long-term workflows and records workflow completion, and cancellation or closing of a case. Documents dates and times for each activity performed;

2. Allow the DSHS Clinical Care Coordination staff to initiate specific actions such as creating letters or other documents, to annotate the execution of the step, and to complete the step. Documents dates and times for each activity performed

3. Allow the DSHS Clinical Care Coordination staff to choose individual letters, scans, or other documents to an external provider;

4. Flag records if multiple births or changes are made to birth weight through demographic entry;

5. Allow for documentation of case activities, including the recording of case notes. As the case progresses, the DSHS Clinical Care Coordination staff must be able to record any appropriate notes concerning the case;

6. Capture a set of information associated with case closure including, but not limited to: date of case closure, identity of staff closing case, reason for closure;

7. After the workflow completion, the LIMS allows the DSHS Clinical Care Coordination staff to continue recording contacts, requesting additional tests and recording results and entering notes into the file, and to close the case;

8. Provide the ability to close cases per disorder while allowing cases to stay active when another abnormal test results for a different disorder is still receiving follow up. Provide the ability for a log that specifies the closed disorders with dates, times, and the DSHS Clinical Care Coordination staff ID.

9. Provide the ability to monitor activities for each abnormal disorder tracked. Only allow the case file closed by DSHS staff;

10. Monitors the progress of the case and identifies when the case is:

    a. New - the case has been set up, but no work has begun;

    b. Being worked through the workflow process;

    c. Completed the short-term workflow process and is now in long-term follow-up; and

    d. Closed;

11. Updates patient demographic information within a case while not impacting the original laboratory specimen demographic information;

12. Ability to query DSHS follow-up data that have occurred up to the point of the query;

13. Ability for DSHS Clinical Care Coordination staff to reopen a case and manually select the action/step to re-start the follow-up; and

D. Contractor must provide additional clinical care coordination LIMS Features and Functions to include the following:

1. Captures and provides a data export file for a defined set of fields from diagnosis and long-term forms for the purpose of reporting to national newborn screening organizations;

2. Assigns each screen (*specimen*) a sequential number - Screen 1, Screen 2, Screen 3, up to the number of screens performed on the same baby; and

3. Captures and provides queries and reports for defined sets of fields including those listed below in **Table 6** by disorder. Provide the ability to imported data into a spreadsheet on a scheduled, automated basis.

Table 6

Newborn ID	Mothers First Name
Accession Number Screen 1	Mothers Last Name
Accession Number Screen 2	Address Line 1
Accession Number Screen 3*	Address Line 2
Date of Screen 1	City
Date of Screen 2	State
Date of Screen 3*	Zip Code
Determination Screen 1	DSHS Region
Determination Screen 2	Guardian Phone Number
Determination Screen 3*	Physician Name
Disorder Screen 1	Physician Phone Number
Disorder Screen 2	Specialist Physician Name
Disorder Screen 3*	Specialist Physician Phone Number
Newborns First Name	Diagnosis Name and Code
Newborns Last Name	Date of Diagnosis
Date of Birth	Diagnosis Entered Date
Birth Weight	Treatment Drug
Gestational Age	Treatment Dose
Ethnicity	Treatment Start Date
Sex	Confirmatory Tests and Dates

Up to the number of screens performed on the newborn.

    E. Contractor must provide LIMS functions to support clinical care coordination casework Long Term Follow-up to include the following:

        1. Long term cases have pre-defined workflows similar to initial cases. The workflow defines the sequence and frequency of steps the DSHS Clinical Care Coordination staff must take in long term follow-up on the case;

        2. Diagnosis of a case with one (1) of the specified disorders, automatically moved the case to long term follow up status and workflow;

        3. Long term follow-up fields must incorporate all information and fields completed in short term follow-up, including edited demographic information, diagnosis, specialist physicians, etc.;

        4. Screens in long term workflows are pre-populated with the updated data fields from the initial casework; and

        5. If no data is available, DSHS Clinical Care Coordination staff must be able to update the record with new long-term information once received.

2.4.14 Contractor must provide additional LIMS features and functions to include the following:

A. A statistical module to determine, monitor and evaluate analytical cutoffs that must have the following abilities:

1. To query quantitative test result data for statistical analysis of analyte values with the ability to separate first, second, and to repeat specimens;

2. For DSHS to evaluate potential abnormal cutoffs and the associated performance/impact (*cutoff analyzer population determination and review*);

3. To query all specific analyte marker concentrations for a user defined period of time. Provide query concentration points based on age at collection, birth weight, ethnicity, feed, status, concentration, and specimen status (*initial and retest*), instrument, assay type. With each query, statistically determines standard deviation and percentile ranges defined by user;

4. To query by specific laboratory specimen ID number date range;

5. To query multiple analyte markers from defined specimen set;

6. To export user query results;

7. For user to be able to update the user defined fields to compare impact of alternate cutoff value; and

8. To print a summary document of selected parameters and calculations.

B. Specimen Logistics Module and Functions must include the following abilities:

1. To Scan Parental Decision Forms that contain a barcoded form serial number. This number correlates to an NBS specimen collection kit;

2. To apply the consent received date, a consent ID number, and the consent type (*OK or NO*) to the form serial number and any linked form serial numbers;

3. To identify the latest consent type, consent ID, and consent status received and apply to all linked specimens upon completion of a new link, or upon the processing of an additional decision form with a form serial number associated with any of a grouping of linked specimens;

4. To print barcodes for multiple entered form serial numbers;

5. To manually change any of the associated fields by individual form serial number or by a group of numbers;

6. To generate verification lists of all scanned specimens using the demographic information associated with the form serial numbers prior to completion of processing;

7. To generate lists of specimens in a user identified received date range with a user identified consent type;

8. To track whether a specimen has been destroyed; and

9. To mark a specimen as destroyed or change the specimen destroyed status.

C. Second Tier Testing Modules and Functions must include the following abilities:

1. To receive through Specimen Receiving, on a G1-B Specimen Submission Form and recorded in the LIMS and associated with the patient like other specimens;

2. To record test results in LIMS and create and send result reports ("mailers") through mail, fax, HL7, or existing Web application as determined by DSHS;

3. To post test results against existing cases;

4. To incorporate new second tier tests as requested by DSHS;

5. PKU Monitoring module: Patients diagnosed with PKU have periodic tests to assist with monitoring diet compliance:

    a. The PKUM specimen accession module must assign a PKUM specific specimen ID number for each external specimen received for PKU Monitoring test;

    b. The PKUM demographic entry module must provide for demographic entry using the DSHS G-1B Specimen Submission Form with DSHS approval of captured fields from the G-1B Specimen Submission Form;

    c. Provides a submitter maintenance database to manage submitter billing address, test result reporting method, address, and contact information;

    d. The analytical testing module must provide for direct transfer of test results with conversion from umol/L to mg/dL or must provide for manual entry of test results and must provide for selection of unsatisfactory test codes as needed;

    e. Result reporting descriptions and codes must be DSHS approved; and

    f. Result reporting must provide for a process to initiate generating and printing of final result report, including unsatisfactory results. Result reporting must provide generating of duplicate and revised reports and creating of mailer image as specified in Section 2.4.12 (G); and

6. DNA module: Reflex test for patients identified during testing or diagnosed through the NBS program or as a fee for service for specimens received from outside DSHS:

    a. Current testing includes Hemoglobinopathy, Galactosemia, MCAD, VLCAD, X-ALD, and Cystic Fibrosis DNA Testing;

    b. DNA specimen accession module must provide for specimens to have one (1) or multiple DNA ID numbers assigned and linked to the same NBS specimen ID number. In addition, the accession module must provide for external DNA specimens to be accessioned and assigned external DNA specific ID numbers. The accession module must provide the ability to assign at least one (1) unsatisfactory code to each DNA ID number;

    c. Demographic entry module must provide for demographic entry using the DSHS G-1B Specimen Submission Form with DSHS approval of captured fields from the G-1B Specimen Submission Form;

    d. Analytical testing module must provide for variant pathogenicity interpretation capability and links to reputable variant databases, automatic

and manual entry of DNA results accepting at least six result codes per specimen, easy result release, and report preview prior to printing of final result report; and

 e. DNA module must provide expansion and addition of new DNA tests as requested by DSHS.

D. **Activity Logging/Audit** trail must include the following abilities:

 1. Capture and log pertinent LIMS events;

 2. Provide log and audit information for review by DSHS staff; and

 3. Log and audit information includes, at a minimum, the date, time, and user who performed any change on a demographic field, specimen status, linking status, assay status, test answer status, and result code related to the specimen

E. **Queries and reports** must include the following abilities:

 1. Extracted data for creation of analytical reports pertaining to the various disorders tested by DSHS staff;

 2. Customized reports to meet the needs of DSHS for user to select fields by which to request the data and designed to contain DSHS designated data fields;

 3. DSHS approved standard statistical queries and reports to allow for workflow monitoring and workload processing;

 4. Monthly provider report cards made available;

 5. Provide a minimum of ten (10) reports at no charge to the State, as specified by DSHS NBS Laboratory;

 6. Request for No Charge Reports must use the Change Request Process used for other requested LIMS Application modifications; and

 7. Future LIMS product must provide a query builder application that DSHS staff can use to generate or modify queries and reports.

F. **Remote Data System** must have functions to include the following abilities:

 1. HL7 interface - Contractor must work cooperatively with DSHS staff and must:

  a. Provide bi-directional communication to receive specimen demographic information electronically from a submitter and return results electronically to the submitter using HL7 Version 2.5.1 and HL7 Fast Healthcare Interoperability Resources (FHIR) standards;

  b. Provide HL7 solution to be able to listen for HL7 messages from submitters, parse the messages, manipulate the contents, and put the data into a holding database;

  c. Seamlessly integrate with the existing HL7 messaging solution for NBS and agency-wide public health interoperability solution for the electronic test ordering and results (*The Health Services Gateway*);

  d. Receive Admission Discharge Transfer (ADT) messages and populate patient data prior to specimen order receipt;

e. Receive HL7 test orders in conformance with HL7 Version 2.5.1 Implementation Guide: Laboratory Orders from EHR (LOI);

f. Match order messages to previously received ADT patient data to complete test orders;

g. Receive, at minimum, all demographic fields requested on the demographic portion of the NBS specimen collection kit;

h. After a DSHS specified period of time, provide the ability to send out alert messages to submitters who have not filled an order but have sent in specimens;

i. Send result messages in compliance with College of American Pathologists requirements and in conformance with HL7 Version 2.5.1 Implementation Guide: Lab Results Interface (LRI) unless otherwise approved by DSHS;

j. Provide log files of all incoming and outgoing messages used for auditing purposes;

k. Create new submitter accounts and the ability to update the submitter directory, as needed;

l. Provide alert HL7 error messages to be sent from computer when system errors occur. This requirement is for internal and external users;

m. Provide solutions to assure that patient files cannot be permanently deleted or corrupted from operation of the program;

n. Allow users to make corrections to bad HL7 messages and resubmit them;

o. Detect invalid HL7 messaging formats and reject these HL7 formats by sending alert error messages and ACK HL7 messages to the submitter and

p. Provide ability to schedule HL7 activities in coordination with DSHS staff;

2. Secure Web application, Future LIMS product - Contractor must work cooperatively with DSHS staff and must include the following abilities:

a. Provide the ability for electronic test ordering through entry of all required demographic information;

b. Provide capability to access previously submitted ADT information and complete remaining demographic entry;

c. Demographic screen must be a single screen display and allow multiple options for different form serial number years;

d. Demographic Entry portion must contain alerts and validations at the tab, save, and submit levels;

e. Provides the ability to print demographic information labels to DSHS or submitter printer in a format acceptable to DSHS. Format includes at a minimum size of label, data fields printed on label and the design of the label. Design specifications and images of the label can be found in Section 2.8 Resource E;

f. Allows entry of all current demographic information from current specimen collection kit into the demo entry screen in the same order found on the demographic form of the specimen collection kit;

g. Provides access to result reports and keeps track of end user test orders, results searches, viewed and down loaded PDF's results;

h. Provides access to monthly submitter report cards;

i. Provides reports to DSHS and submitters for the tracking of specimen submissions;

j. Provides end user alerts and summaries on delayed specimen collections, delayed specimen shipping, specimen receipt, and new result report availability;

k. Provides capability to order specimen collection kits and related supplies;

l. Allows tracking and monitoring of kit orders;

m. Provides capability to apply for new DSHS submitter ID number;

n. Provides controls to limit access to result reports to comply with HIPAA requirements;

o. Provides self-service end user new account activation and existing account deactivation. This feature must comply with DSHS IT security requirements;

p. Provides self–service end user password reset;

q. Provides self-service end user account unlock;

r. Provides password change reminders;

s. Locks inactive end user accounts that are inactive for a set period of time;

t. Provides automated end user account lockout function after several failed login attempts;

u. Uses Section 508 Standards for guidance for designing accessible web pages for accessibility to people with disabilities at https://www.section508.gov/;

v. Ensures internet enabled remote user interface applications are fully compatible and function properly with all major internet browsers and their various versions, including the most recent version and the version prior or as required by DSHS and up to the current version with all current security updates applied throughout the Contract terms and any renewals;

w. Ensures that the Browser-based Result Viewer displays the name of the submitter/user after successfully login;

x. Securely delivering an identical representation of the final result report image to the requesting submitter through the Browser-based Result Viewer search capabilities;

y. Provides the ability for information from a single submitter with different locations to be linked together;

    z.   Provides the ability to produce Statistical Reports that must show which submitters have logged into the system;

    aa.   Encrypt confidential information via a secure web-based application and must be accessible only with a minimum of 128-bit SSL encryption; and

    bb.   Ensures the remote data system has protection against SQL Injection.

3. Additional Remote Data System Capabilities - Contractor must work cooperatively with DSHS staff to:

    a.   Provide the capability to capture clinical follow-up data through forms in HL7 Clinical Document Architecture (CDA) and FHIR formats; and

    b.   Receive updated patient Primary Care Provider (PCP) information from ADT messages.

2.4.15 Change Request and Test Verification Process

A. Contractor must follow the current change request process in cooperation with DSHS. Any changes or edits of the process must be mutually agreed upon by the parties with DSHS final approval.

1. DSHS initiates the request in the following way:

    a.   A verbal or written request for a change; or

    b.   A service request initiated by DSHS notification is to be a change by the Contractor;

2. The Contractor must provide a request for services template for both written and verbal requests. DSHS will complete a request for services, detailing the requirements in writing and submit via contact information or tracking system;

3. Upon receipt confirmation, a Tracking Number must be issued to DSHS;

4. Upon receipt of the request for services, the Contractor may initiate a conference call to obtain a clear understanding of DSHS requirements, scope and timeframe required;

5. The Contractor must produce a written response within ten (10) calendar days upon receipt of the request. This response must either be:

    a.   An acknowledgement including details of the inability to fulfill the change;

    b.   An acknowledgement of the ability to fulfill the change free of charge with the next scheduled release of the impacted module; or

    c.   An acknowledgement of the ability to fulfill the change, complete with an estimate which must include:

        1)   The estimated number of hours required to complete the task;

        2)   An estimate of the timeframe required to complete the services. This must include an estimation of beginning date, duration and date of completion of the project. The estimated time to complete will depend on the availability of resources and the complexity of the feature requested;

      3) The number of resources required by DSHS staff to provide specification information and staff resources to test and accept the services; and

      4) The cost to DSHS;

6. DSHS will review the estimate within ten (10) calendar days upon receipt of the estimate;

7. DSHS and the Contractor must discuss the estimate and project by conference call;

8. When both the Contractor and DSHS agree on the services requested, resources required, timeframe, cost and acceptance criteria, both the Contractor and DSHS authorized agents must sign the estimate, which must include any negotiated points accepted by both DSHS and the Contractor;

9. There must be no charge for additional hours required to complete the change request if the change request is not completed within the number of hours listed in the Contractor estimate;

10. Upon satisfactory implementation of the requested change, DSHS will validate the change and sign an acceptance document stating the request is complete and accepted; and

11. DSHS has the authority to determine when an amendment to the Contract, and not a change request, is required.

B. Contractor must seek DSHS approval of any modifications to LIMS and any related cost prior to implementation.

C. After receiving approval, Contractor must use the test environment to pre-validate all new and additional modifications to the system/application prior to release to DSHS.

D. Contractor must provide end user validation within a test environment for all modifications to the system/application.

E. DSHS will perform final, comprehensive validation of the LIMS application configuration prior to moving and using the software in a live production environment.

2.4.16 Contractor must provide LIMS training to include the following:

A. Develop and provide training, curriculum, manuals and materials for instructor-led hands on training sessions;

B. Coordinate the scheduling of training sessions with DSHS Lab Managers to ensure training occurs thirty (30) calendar days prior to all upgrades, new LIMS software and module, customization or features and prior to installation or changes of the software;

C. Provide a qualified trainer knowledgeable of DSHS specific customized LIMS software and processes;

D. All training curriculum, materials and manuals must have final written approval from DSHS Lab Managers. Contractor must submit to DSHS NBS Laboratory Managers copies of the final curriculum, materials and manuals for acceptance by DSHS no less than ten (10) calendar days prior to the scheduled training;

E. Train the trainer training for DSHS NBS Laboratory and follow-up staff for all upgrades, new LIMS software and module, customization or features to coincide with installation. Training must focus on how to effectively operate LIMS daily in the DSHS environment;

F. Yearly comprehensive and refresher training to DSHS designated administrative staff to include an overview of the applicable LIMS software and Server database structures. Training must focus on how DSHS can fully support and maintain the LIMS application in real-time and on-site, writes, edits, and runs database queries and provide data extractions. Training must include documentation on user setups, including complete security and privileges overview and set up of groups, individuals and module restrictions and reporting and validation privileges;

G. Provide detailed documentation in a User Guide that reflects step by step processes on how to utilize the LIMS software application reflecting DSHS specific customization at the training;

H. Provide training in divided specific classes for designated DSHS staff to receive training relevant to their job functions. Contractor agrees to provide as a minimum two classes per curriculum or as mutually agreed to by the parties;

I. Provide training on-site at DSHS. Agendas, training, and schedules must be mutually agreed to between DSHS and the Contractor;

J. Provide user hard copies and electronic manuals and guides;

K. Provide training certificate to each DSHS staff member that completes training; and

L. Future LIMS product - Provide a web based online help system and tutorial, for the Web application, accessible by local and remote submitters though an Internet connection. The self-paced user tutorials for DSHS and external users must be available 24 hours, 7 days a week.

2.4.17 LIMS Application Maintenance and Support

A. Contractor must provide, with consultation of DSHS IT, on-going LIMS Application and maintenance and technical support to include the following:

1. Within 6 months of the Contract execution and upon the successful hiring and training by PerkinElmer, a full-time LIMS engineer located onsite at the DSHS NBS Laboratory Monday through Friday 8:00 am to 5:00 pm, CT;

2. DSHS will continue to perform and execute all backup maintenance activities for current software solution and Contractor will assist and consult as needed;

3. The ability to receive, accession, process, test and report results for DSHS received newborn screening specimens, second tier specimens, and monitoring specimens;

4. Bi-directional equipment communication for equipment provided as part of this RFP as well as with DSHS provided analytical equipment including but not limited to Cystic Fibrosis DNA, Hb-HPLC and SCID testing equipment;

5. HL7 solution to allow DSHS to electronically receive patient demographics and transmit test results;

6. Functions related to kit management, submitter database, positive specimen tracking, specimen level free text note component, specimen logistics, automated and manual linking of the first, second and successive specimens;

7. Functions related to statistical review of results related to quality control tracking and review, and population cut-off analyzer;

8. The ability to send notifications, in real-time, of each abnormal result to DSHS follow-up staff via LIMS software module;

9. The ability to maintain electronic record for each newborn that requires follow-up including, but not limited to: DSHS specified follow-up actions, documentation of contacts with medical personnel and family, and all information gathered from the specimen collection form, DSHS test results, internal and externally processed diagnostic test results, newborn's health care providers, changes to demographic data and health care providers, diagnosis, closure code, treatment and comments;

10. The ability to maintain follow-up case workflow (*both automated and manual steps*) including staff assignment, workflow triggers, actions, tracking, cancellation or closing;

11. The ability to ensure cases that are closed prematurely can be re-opened without delay, and activities are re-established by the user manually selecting the action/step to re-start;

12. The ability for queries and pre-defined reports, including the ability for DSHS staff to query the database and to pull data to export files and extractions;

13. Maintaining DSHS records retention policies;

14. Future LIMS product must provide a data archiving solution that allows DSHS easy access to older data;

15. Maintaining a test environment with data refreshed quarterly unless otherwise authorized by DSHS;

16. Contractor must use all reasonable efforts to remedy any system anomaly after the Customer identifies and notifies Contractor of any such system anomaly;

17. Contractor must provide a tracking number for each support request;

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18.   Contractor must develop and maintain a LIMS Application Maintenance and Support service plan to include specific routine maintenance processes as well as a proposal for response to system anomalies. Issue response plan must include after hours, weekends, and holidays;

19.   A maintenance proposal that must contain, at a minimum, system back-up plan, daily, weekly, monthly, another period system maintain plan; and.

20.   A support proposal that must contain, at a minimum, multiple levels of anomalies such as fatal error, critical error, moderate error, minor error, and system enhancement.

B. Data Archive and Retrieval to be provided with future LIMS product.

1. To aid in the ongoing performance of the LIMS, DSHS will provide specific aging criteria for moving aged data from the active database to an archive.

2. Archive data must remain accessible to searches and must be able to be merged with active data for historical report generation and statistical analysis

C. On-Site (DSHS) Access

1. For work performed outside of normal DSHS business hours, the Contractor must request the DSHS representative's availability in advance. Availability to work outside of normal DSHS business hours is subject to DSHS approval, with the understanding that if the DSHS representative is not available there may be a delay System Anomaly resolution.

2. Excluding events agreed to by DSHS as bona-fide emergencies or disasters, the Contractor must provide the DSHS representative three calendar days advance-notice of intent to perform work on site outside of normal DSHS business hours of 8AM – 5PM CT.

2.5 Backup Plan for Ensuring Continuity of Service

Contractor must maintain a backup plan for handling emergency situations that may affect the operations of the DSHS NBS Laboratory. Backup plan must include resources available to Contractor to assist DSHS and address LIMS, equipment, testing reagents and consumables emergencies including the following:

2.5.1   Contractor must provide, at no additional charge, a refrigerated truck capable of maintaining acceptable temperature range for storage of temperature-sensitive testing reagents in case of emergencies, including method of monitoring and recording the temperature in the refrigerated portion of the truck.

2.5.2   Contractor must provide back-up testing services in case of emergencies, including information as to disorder names, methodologies, specimen shipping and reporting logistics, turnaround time, daily specimen volume capacity, and cost per specimen.

2.6 Transition Plan

Following the base term and any allowable extensions, DSHS 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.

2.6.1 Within sixty (60) calendar days of an executed Contract, the Contractor must develop and submit a detailed transition plan to DSHS for approval, including approximate implementation costs chargeable to DSHS, for all activities in Section 2.6.1-2.6.6. The plan must include the following requirements:

A. Contractor must cooperate with DSHS and any of its designated representatives to allow DSHS and any of its designated representatives to build and implement any needed bi-directional interfaces, including, but not limited to: equipment-to-LIMS database and LIMS database-to-different database;

B. Contractor must continue to provide analytical equipment, testing reagents, consumables, technical support, and equipment maintenance throughout the transition period until validation of the new equipment and in normal operation mode;

C. Contractor must provide LIMS modifications to support any potential new equipment and new tests, including, but not limited to result codes, queries, and testing and follow-up algorithms;

D. Contractor must participate in meetings or conference calls as directed by DSHS to discuss transition issues;

E. Contractor must adhere to the agreed upon transition timelines; and

F. Once the DSHS NBS Laboratory is functioning with the new Contractor, the Contractor must remove their equipment from the DSHS NBS Laboratory, as directed by DSHS.

2.6.2 Contractor must provide access to the newborn screening data, as directed, as the data are stored in the newborn screening databases including any methods, parameters, quality control and assay data as stored on the equipment to include the following:

A. Contractor must provide a complete and accurate mapping document to DSHS that lists the folder locations for all data files and images associated with the NBS data;

B. Contractor must provide a data dictionary listing, which at a minimum must include tables and descriptions, fields and descriptions, and database diagram showing the data mapping;

C. Contractor must cooperate with DSHS and any of its designated representatives to allow DSHS and any of its designated representatives to build, implement and maintain in a secure manner any needed bi-directional interfaces for communication, including, but not limited to: equipment-to-LIMS database, HL7, and LIMS database-to-database-to-another database;

D. Contractor must participate in meetings or conference calls as needed to discuss the transition of data to DSHS and/or any of its designated representatives;

E. Contractor must provide consultation and assistance, as directed by and chargeable to DSHS, to DSHS and any of its designated representatives while data are physically transferred from the LIMS databases to a different database;

F. Contractor must continue to provide LIMS support and maintenance chargeable to DSHS throughout the transition period until validation of the new LIMS and in normal operation mode; and

G. Contractor equipment, workstations, LIMS software system, and databases (*excluding data*) must not be directly transferred by DSHS to another entity.

2.6.3 Contractor must provide DSHS, for new Contractor's use, data and reports derived or developed by DSHS and stored in the LIMS software.

2.6.4 Contractor must begin shipping, transmitting or providing access to all appropriate materials and data to DSHS or new Contractor, as directed by DSHS, within ten (10) calendar days of announcement of award at the new Contractor's expense for data processing and production, packing and shipping.

2.6.5 Contractor must be responsible for providing the services identified in the Contract until all records have been completely transferred to the new Contractor.

2.6.6 Contractor is responsible for performing due diligence to ensure that all the transition activities are completed during the contract transition.

2.7 Failure to Deliver

2.7.1 DSHS will monitor the performance of the Contract issued under this RFP. The Contractor must 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.

2.7.2 Scope of Work/Specifications including, but not limited to, testing kit components, equipment, replacement kit components and equipment must be delivered and installed, repaired or replaced by the timeframes specified in this Contract to ensure the DSHS NBS Laboratory's ability to maintain current testing, reporting and clinical care coordination activities. If the Contractor fails to deliver the required deliverables and it impacts the DSHS NBS Laboratory's ability to perform newborn screening of all currently screened disorders or at current testing levels, the Contractor must supply backup testing and follow-up services, at no cost to DSHS.

2.7.3 All testing reagents, consumables, testing equipment, and workstations are subject to inspection and testing by the state. Authorized DSHS personnel will have access to a Contractor's place of business for the purpose of inspecting contracted merchandise. Testing reagents, testing equipment and workstations must meet performance criteria listed in this Statement of Work. If performance criteria are not met and problems

resolution process does not rectify the issue, the Contractor must replace testing reagents, testing equipment, or workstations at no cost to DSHS.

2.7.4   Training, technical support, problem resolution, and maintenance services listed in this Statement of Work *(includes services performed, material furnished or utilized in the performance of services, and workmanship in the performance of services)* will be subject to inspection and test by DSHS, to the extent practical at all times and places during the term of the Contract. All inspections by the DSHS will be made in such a manner as not to unduly delay the work. If any services performed hereunder are not in conformity with the requirements of this Contract, DSHS will 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 insure future performance of the services in conformity with the requirements of the Contract, DSHS will have the right to either:
1. terminate the Contract for cause as provided for in <u>Attachment C, UTCs v3.0.</u>

2.8 Insurance

2.8.1 Required Insurance

A. **General Insurance Requirements**
1. Contractor shall carry insurance in the types and amounts indicated in this Attachment for the duration of the Contract. The insurance shall be evidenced by delivery to DSHS of certificates of insurance executed by the insurer or its authorized agent stating coverages, limits, expiration dates and compliance with all applicable required provisions. Upon request, DSHS, and/or its agents, shall be entitled to receive without expense, copies of the policies and all endorsements.
2. Contractor shall update all expired policies prior to submission for monthly payment. Failure to update policies shall be reason for withholding of payment until renewal is provided to DSHS.
3. Contractor shall provide and maintain all insurance coverage with the amounts described throughout the life of the Contract.
4. Failure to maintain insurance coverage, as required, is grounds for suspension of work for cause.
5. Contractor shall deliver to DSHS true and complete copies of certificates and corresponding policy endorsements upon award.
6. Failure of DSHS to demand such certificates or other evidence of Contractor's full compliance with these insurance requirements or failure of DSHS to identify a deficiency in compliance from the evidence provided shall not be construed as a waiver of Contractor's obligation to maintain such insurance.
7. The insurance and insurance limits required herein shall not be deemed as a limitation on Contractor's liability under the indemnities granted to DSHS in the Contract.
8. The insurance coverage and limits established below shall not be interpreted as any representation or warranty that the insurance coverage and limits necessarily will be adequate to protect Contractor.

9. Coverage shall be written on an occurrence basis by companies authorized and admitted to do business in the State of Texas and rated A or better by A.M. Best Company or similar rating company or otherwise acceptable to DSHS.

B. Policies must include the following clauses, as applicable:

1. This insurance shall not be canceled, materially changed, or non-renewed except after thirty (30) days written notice has been given to DSHS.
2. It is agreed that Contractor's insurance shall be deemed primary with respect to any insurance or self-insurance carried by DSHS for liability arising out of operations under the Contract with DSHS. Health and Human Services Commission, its officials, directors, employees, representatives, and volunteers are added as additional insureds as respects operations and activities of, or on behalf of the named insured performed under Contract with DSHS. The additional insured status must cover completed operations as well. This is not applicable to workers' compensation policies.
3. A waiver of subrogation in favor of Health and Human Services Commission shall be provided in all policies.
4. Without limiting any of the other obligations or liabilities of Contractor, Contractor shall require each Subcontractor performing work under the Contract, at Subcontractor's own expense, to maintain during the term of the Contract, the same stipulated minimum insurance including the required provisions and additional policy conditions as shown above.
5. As an alternative, Contractor may include its Subcontractors as additional insureds on its own coverage as prescribed under these requirements. Contractor's certificate of insurance shall note in such event that Subcontractors are included as additional insureds and that Contractor agrees to provide workers' compensation for Subcontractors and their employees. Contractor shall obtain and monitor the certificates of insurance from each Subcontractor in order to assure compliance with the insurance requirements. Contractor must retain the certificates of insurance for the duration of the Contract plus five (5) years and shall have the responsibility of enforcing these insurance requirements among its Subcontractors. Owner shall be entitled, upon request and without expense, to receive copies of these certificates.

C. Specific Insurance Coverage Required.

1. **Workers' Compensation.** Insurance with limits as required by the Texas Workers' Compensation Act, with the policy endorsed to provide a waiver of subrogation in favor of Health and Human Services Commission, employer's liability insurance of not less than:

   $1,000,000 each accident;

   $1,000,000 disease each employee; and

   $1,000,000 disease policy limit.

Workers' compensation insurance coverage must be provided for all workers at all tier levels and meet the statutory requirements of Texas Labor Code.

2. **Commercial General Liability Insurance**. Including premises, operations, independent Contractor's liability, products and completed operations and contractual liability, covering, but not limited to, the liability assumed under the indemnification provisions of this Contract, fully insuring Contractor's liability for bodily injury (including death) and property damage with a minimum limit of:

$2,000,000 per occurrence;

$4,000,000 general aggregate;

$10,000 Medical Expense each person;

$2,000,000 Personal Injury and Advertising Liability;

$4,000,000 products and completed operations aggregate;

$50,000 Damage to Premises Rented to You; and

Coverage shall be on an "occurrence" basis.

The term "You" as reference in Subsection above, means the Contractor.

3. **Comprehensive Automobile Liability Insurance**, covering owned, hired, and non-owned vehicles, with a minimum combined single limit for bodily injury (including death) and property damage of $1,000,000 per accident. No aggregate shall be permitted for this type of coverage.

Umbrella Liability Insurance. Contractor shall obtain, pay for and maintain umbrella liability insurance during the Contract term, insuring Contractor for an amount of $25,000,000 per occurrence; $25,000,000 general aggregate; $25,000,000 products and completed operations aggregate that provides coverage excess of the Commercial General Liability, Comprehensive Automobile Liability and Employers Liability coverages required hereinabove.

4. **Cyber/Privacy Liability** -. Contractor shall provide Cyber/Privacy Liability Insurance to cover risk of loss to electronic data. The policy must include coverage for a "Cyber Security Breach" as defined as "any unauthorized: access to, use or misuse of, modification to the network, and/or denial of network resources by cyber-attacks perpetrated by a third party or rogue employee through any electronic means, including malware, viruses, worms, and Trojan horses, spyware and adware, zero-day attacks, hacker attacks and denial of service attacks." Nothing herein shall relieve Contractor of its financial obligations set forth in the Attachment F, DUA v8.5 if Contractor fails to maintain insurance in an amount sufficient to cover Contractor's financial obligations in the DUA.

Cyber Liability Insurance $5,000,000 Claim/$5,000,000 Aggregate.

5. **Professional Liability Insurance**. Contractor shall obtain, pay for and maintain professional liability errors and omissions insurance during the Contract term, insuring Contractor for an amount of not less than $5,000,000 per claim; $5,000,000 aggregate covering the following professional services: Installation, maintenance, repair, calibration, validation, inventory management of laboratory machines, computers, and equipment, including, but not limited to laboratory diagnostic and analytical instruments; Laboratory consulting and support services; Image analysis software, QA/QC Software, Newborn/Prenatal screening software, Instrument Control Software, Instrument upgrade software, Computer control and monitoring software, Data visualization and analytics software, Research & Development software; Data analysis.

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

III. PERFORMANCE MEASURES

DSHS will monitor Contractors' performance of the requirements in this Attachment and compliance with the Contract's terms and conditions.

IV. INVOICE AND PAYMENT

4.1 Contractor will request payments using the State of Texas Purchase Voucher (Form B-13) at http://www.dshs.state.tx.us/grants/forms.shtm. Voucher and any supporting documentation will be mailed or submitted by fax or electronic mail to the address/number below.

Department of State Health Services
Claims Processing Unit, MC 1940
1100 West 49th Street
P.O. Box 149347
Austin, TX 78714-9347
FAX: (512) 458-7442
EMAIL: invoices@dshs.texas.gov and CMSinvoices@dshs.texas.gov

4.2 Contractor will be paid based on set price and in accordance with the Attachment B, Price List of this Contract.

4.3 Contractor will submit requests for reimbursement (Form B-13) after the date in which goods are received or services provided.

4.4 Any request for reimbursement submitted prior to the date goods are received or services provided will be returned to the Contractor unpaid.

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4.5 In the event a cost reimbursed under the Contract is later determined to be unallowable then the Grantee will reimburse DSHS for that cost.

Attachment B
Price & Equipment List

FY 21-22 Price List

Pricing to be inclusive of equipment rental.

* Approximate quantity listed is estimate and not to be construed as a minimum or maximum

Contract will be amended to reflect any change to services or for any change to Grand Total amount of Contract

| | | | | Grand Total | $19,644,603.71 | $18,915,222.71 |
| | | | | | FY21 | FY22 |

Section 1 -Analytical Test Kits, Consumables and Accessories

Part Number	Part Description	Approximate Quantity per year *	Contract Unit Price	FY21	FY22
B065-01C	AUTODELFIA NEONATAL THYROXINE (T4) KIT,	550/0	$1,591.55	$875,352.50	$0.00
B032-02C	AUTODELFIA NEONATAL HTSH KIT, S&S 903	104/0	$1,591.55	$165,521.20	$0.00
B005-212	AUTODELFIA NEONATAL IRT	1300/600	$1,591.55	$2,069,015.00	$954,930.00
13806419	Extra IRT Buffer	1300/600	$0.00	$0.00	$0.00
1235-402	EPPENDORF PIPETTE TIPS	250	$236.45	$59,112.50	$59,112.50
1235-411	NEW DILUTION VESSELS (100/PKG)	250	$50.88	$12,720.00	$12,720.00
B117-100	AUTODELFIA WASH CONCENTRATE (250ML) 8 BOTTLES	250/150	$354.66	$88,665.00	$53,199.00
B118-100	AUTODELFIA ENH.SOL. (250ML) BOTTLES	350/150	$1,112.62	$389,417.00	$166,893.00
FR-9360	RESOLVE-HB NEONATAL HEMOG SCR KT3600 TST	300	$2,157.40	$647,220.00	$647,220.00
3305-001U	GSP 17A-OHP	1300	$1,564.99	$2,034,487.00	$2,034,487.00
4080-0010	GSP Wash (T4,TSH, IRT,17OHP,Biotinidase) (1000mL ea)	300/400	$188.24	$56,472.00	$75,296.00
3304-0010	GSP Inducer (T4,TSH, IRT,17OHP,Biotinidase) (12 x 500mL)	200	$1,092.62	$218,524.00	$218,524.00
3303-001U	GSP GALT	1200	$1,050.60	$1,260,720.00	$1,260,720.00
2021-4010	Low Volume Tips (960 - 50uLpipet tips)	150	$168.98	$25,347.00	$25,347.00
4076-0010	GSP GALT Microplates (clear - 50/pkg)	288	$210.04	$60,491.52	$60,491.52
3060-0010	GSP (Maintenance) Test Kit	36	$496.41	$17,870.76	$17,870.76
NG-1100	GALT reagent kit, 4000 patient	48	$0.00	$0.00	$0.00
R-BAR-RIBBON	Sato M84 Pro BarCode generator - 4" Black Wax BarCoder bbon	2	$96.37	$192.74	$192.74
L-Vicbarplate	Sato M84 Pro BarCode generator - BarCode labels 2.323", 10,000/roll	5	$504.79	$2,523.95	$2,523.95
3044-001U	NeoBase2 kit	1200	$5,797.17	$6,956,604.00	$6,956,604.00
3045-0010	NeoBase2 Non-derivitized assay Solutions	1200	$0.00	$0.00	$0.00
3046-0010	NeoBase2 Succinylacetone assay	1200	$553.38	$664,056.00	$664,056.00
3984010	Wallac Precise Tips (20 racks per case) for Apricot Personal Pipettor	22	$184.90	$4,067.80	$4,067.80
3033-0010	MICROPLATES, V-TRUNCATED CLEAR 100/PK	60	$116.97	$7,018.20	$7,018.20
13808362	Adhesive, microplate covers, 10/pkg	200	$77.40	$15,480.00	$15,480.00
11951343	X-type plunger for Waters 2777C Autosampler; 3/pkg	15	$630.99	$9,464.85	$9,464.85
11950742	Needle Seal, gauge 22, for Waters 2777C Autosampler; 10/pkg	100	$450.87	$45,087.00	$45,087.00
11951342	100 ul SyringeX, gauge 22 for Waters 2777C Autosampler, each	10	$605.31	$6,053.10	$6,053.10
1445-2150	Foil Cutter for Waters 2777C Autosampler; each	5	$91.78	$458.90	$458.90
11950984	BS008 O-ring for TQD; 5/pkg	5	$28.69	$143.45	$143.45
11950988	GVF Graphite ferrule for Quattro Micro; 2/pkg	60	$150.29	$9,017.40	$9,017.40
11950989	PTFE liner tube for TQD; 5/pkg	24	$115.88	$2,781.12	$2,781.12
11950868	TUBE SS ESI CAPILLARY (125UM ID) for TQD; each	160	$195.03	$31,204.80	$31,204.80
11950876	Sleeve, ESI Conductive (in capillary assembly) for TQD; each	60	$53.92	$3,235.20	$3,235.20
SX016316	PEEK Tubing, red 1/16 OD X .005 ID, 5' for Quattro Micro; each	150	$33.27	$4,990.50	$4,990.50
1445-4020	In-Line Filter Casing-stainless steel filter assembly for TQD; each	2	$44.74	$89.48	$89.48
1445-4030	In-Line Filter Frit (Filter end fitting PEEK, 2um) for Quattro Micro; 10/pkg	30	$92.93	$2,787.90	$2,787.90
11950880	PEEK one-piece finger tight fitting for TQD; 10/pkg	5	$84.13	$420.65	$420.65
11950867	ASSY ESI PROBE TIP for TQD; each	25	$623.89	$15,597.25	$15,597.25
11951501	ZQ Cone Gas Nozzle for TQD; each	10	$949.50	$9,495.00	$9,495.00
11951502	ZQ Sample Cone for TQD; each	20	$620.61	$12,412.20	$12,412.20
11950882	O-Ring, 12 X 1.5, VITON (1PK) (between cone-gas and sample cones) for TQD; each	10	$134.23	$1,342.30	$1,342.30
11951243	O-Ring, VITON (Ion Source chamber door) for TQD; each	2	$61.95	$123.90	$123.90
11950864	Peek Union for TQD; 2/pkg	8	$396.95	$3,175.60	$3,175.60
11950731	Ultragrade 19 or Inland Q45 vacuum pump oil for TQD; each	10	$160.62	$1,606.20	$1,606.20
3302-001U	GSP T4	1035/750	$1,564.99	$1,619,764.65	$1,173,742.50
3301-001U	GSP TSH	1035/1300	$1,564.99	$1,619,764.65	$2,034,487.00
3306-001U	GSP IRT	0/700	$1,564.99		$1,017,243.50

Part Number	Part Description	Approximate Quantity per year *	Contract Unit Price		
3307-001U	GSP Biotinidase	600	$1,000.00		$600,000.00
NC-2225	MICROPLATE, BLACK, FLAT BOTTOM 25/PK	60	$61.41	$3,684.60	$3,684.60
21402195	TIP GILSON BioRobotix250UL NS CLR 960/PK	16	$89.84	$1,437.44	$1,437.44
1064-05-8	Disposable Automation Reservoir (20 per case) for Apricot Personal Pipettor	3	$248.57	$745.71	$745.71
6000664	150 ml reagent trough for Multiprobe; 50/box	1	$78.73	$78.73	$78.73
1648025	500 ul Syringe (glass tube & plunger w/tip) for Multiprobe; each	8	$111.35	$890.80	$890.80
2118-0010	MigeleTM Gel Electrophoresis Unit (IVD)	4	$7,200.00		$28,800.00
CWP-2000	PROGRAMMABLE POWER SUPPLY (110 V / 220	2	$5,400.00	$10,800.00	$10,800.00
Section 1 - Subtotal				**$19,047,531.55**	**$18,268,150.55**

Section 2 - Items for Laboratory Information Management System Software, Support and Maintenance

Part Number	Part Description	Approximate Quantity per year *	Contract Unit Price		
5003-0530	NEONATAL SOFTWARE SUPPORT AND MAINTENANCE FEE	12	$19,006.01	$228,072.12	$228,072.12
5003-0530	HL7 Inbound/Outbound Monthly Support fee	12	$1,583.33	$18,999.96	$18,999.96
5003-0530	Dedicated On-Site Software Engineer	12	$20,833.34	$250,000.08	$250,000.08
5003-0530	NBS PE LIMS upgrade configuration	1	price is split between years ($250,000 total)	$100,000.00	$150,000.00
Section 2 - Subtotal				**$597,072.16**	**$647,072.16**

Section 3- Items for proposed new Solutions for inclusion upon DSHS request

Part Number	Part Description	Approximate Quantity per year *	Contract Unit Price		
5003-0530	LIMS electronic reporting configuration	1	$150,000.00	$150,000.00	$150,000.00
5003-0530	LIMS electronic reporting Monthly support fee	1	$4,333.33	$4,333.33	$4,333.33
5003-0530	Scanning Module	1	$15,000.00	$15,000.00	$15,000.00
5003-0530	Evoya LIMS Monthly Support fee	12	$2,425.00		$29,100.00
5003-0530	Emergency Testing and Reporting Services	14400	$75.00	$1,080,000.00	$1,080,000.00
5003-0310	NEONATAL SOFTWARE CUSTOMIZATION SERVICE (WITH OPTION TO PURCHASE HOURS AS NEEDED BY DSHS)	600	$191.20	$114,720.00	$114,720.00
BC006237	Qsight 225 MSMS for optional second tier testing	1	$250,000.00	$250,000.00	
CLS145301	Zephyr liquid handling to replace Apricot	5	$0.00	$0.00	
	NeoMDx, cost per sample		$2.49		
	The NeoLSD MSMS Kit includes all equip. and consumables needed, not to exceed $4.00 per sample				

List of Equipment to be provided by PerkinElmer Health Science, Inc.

Part Number	Description of Installed Instrument Provided	Number of installed units
1235-501	AutoDELFIA Plate Processor	10
2021-0010	Genetic Screening Processor	9
1296-071	DBS Puncher	5
2081-0010	Panthera Puncher	15
1445-0020	TQD MSMS system	11
	2777C Sample Manager	11
	1525u Binary Pump System	11
1296-0050	Trinest Incubator/Shaker	20
YJL8001	Janus G3 Expanded 8-tip	2
1003-0190	Powervar UPS system	12
1420-020	Victor Plate Reader	1
MS02420	Apricot Pipettor	2

Health and Human Services (HHS)

Uniform Terms and Conditions - Vendor

Version 3.0

Published and Effective - November 7, 2019

Responsible Office: Chief Counsel

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ARTICLE I. DEFINITIONS AND INTERPRETIVE PROVISIONS

1.1 DEFINITIONS

As used in this Contract, unless the context clearly indicates otherwise, the following terms and conditions have the meanings assigned below:

"Amendment" means a written agreement, signed by the Parties, which documents changes to the Contract other than those permitted by Work Orders.

"Attachment" means documents, terms, conditions, or information added to this Contract following the Signature Document or included by reference and made a part of this Contract.

"Contract" means the Signature Document, these Uniform Terms and Conditions, along with any Attachments, and any Amendments, purchase orders, or Work Orders that may be issued by the System Agency, to be incorporated by reference for all purposes.

"Contractor" means the Party selected to provide the goods or Services to the State under this Contract.

"Deliverable" means a Work Product(s), including all reports and project documentation, prepared, developed, or procured by Contractor as part of the Services under the Contract for the use or benefit of the System Agency or the State of Texas.

"Effective Date" means the date agreed to by the Parties as the date on which the Contract takes effect.

"Federal Fiscal Year" means the period beginning October 1 and ending September 30 each year, which is the annual accounting period for the United States government.

"GAAP" means Generally Accepted Accounting Principles.

"GASB" means the Governmental Accounting Standards Board.

"Goods" means supplies, materials, or equipment.

"Health and Human Services Commission" or "HHSC" means the administrative agency established under Chapter 531, Texas Government Code, or its designee.

"Health and Human Services" or "HHS" includes the Department of State Health Services (DSHS), in addition to the Health and Human Services Commission.

"HUB" means Historically Underutilized Business, as defined by Chapter 2161 of the Texas Government Code.

"Intellectual Property Rights" means the worldwide proprietary rights or interests, including patent, copyright, trade secret, and trademark rights, as such rights may be evidenced by or embodied in:

    i.   any idea, design, concept, personality right, method, process, technique, apparatus, invention, discovery, or improvement;

ii.   any work of authorship, including any compilation, computer code, website or web page design, literary work, pictorial work, or graphic work;

iii.   any trademark, service mark, trade dress, trade name, branding, or other indicia of source or origin;

iv.   domain name registrations; and

v.   any other proprietary or similar rights. The Intellectual Property Rights of a Party include all worldwide proprietary rights or interests that the Party may have acquired by assignment, by exclusive license, or by license with the right to grant sublicenses.

"Parties" means the System Agency and Contractor, collectively.

"Party" means either the System Agency or Contractor, individually.

"Project" means the goods or Services described in the Signature Document or a Work Order of this Contract.

"Scope of Work" means the description of Services and Deliverables specified in the Contract and as may be amended.

"Services" means the tasks, functions, and responsibilities assigned and delegated to Contractor under the Contract.

"Signature Document" means the document executed by both Parties that specifically sets forth all of the documents that constitute the Contract.

"Solicitation" means the document issued by the System Agency (including any published addenda, exhibits, and Attachments) under which the goods or Services provided under the Contract were initially requested, which is incorporated by reference for all purposes in its entirety.

"Solicitation Response" means Contractor's full and complete response (including any Attachments and addenda) to the Solicitation, which is incorporated by reference for all purposes in its entirety.

"State Fiscal Year" means the period beginning September 1 and ending August 31 each year, which is the annual accounting period for the State of Texas.

"State of Texas *Textravel*" means the State Travel Management Program through the Texas Comptroller of Public Accounts website and Texas Administrative Code, Title 34, Part 1, Chapter 5, Subchapter C, Section 5.22, relative to travel reimbursements under this Contract, if any.

"Subcontract" means any written agreement between Contractor and a third party to fulfill the requirements of the Contract. All Subcontracts are required to be in writing.

"Subcontractor" means any individual or entity that enters a contract with the Contractor to perform part or all of the obligations of Contractor under this Contract.

"System Agency" means HHSC or any of the agencies of the State of Texas that are overseen by HHSC under authority granted under state law and the officers, employees, authorized representatives, and designees of those agencies. These agencies include: HHSC and the Department of State Health Services.

"Third Party IP" means the Intellectual Property Rights of any third party that is not a party to this Contract, and that is not a Subcontractor.

"Work" means all Services to be performed, goods to be delivered, and any appurtenant actions performed, and items produced, conceived, or developed, including Deliverables.

"Work Order" means an individually negotiated document that is executed by both Parties and which authorizes a Project, if any, in an indefinite quantity Contract.

"Work Product" means any and all works, including work papers, notes, materials, approaches, designs, specifications, systems, innovations, improvements, inventions, software, programs, source code, documentation, training materials, audio or audiovisual recordings, methodologies, concepts, studies, reports, whether finished or unfinished, and whether or not included in the Deliverables, that are developed, produced, generated, or provided by Contractor in connection with Contractor's performance of its duties under the Contract or through use of any funding provided under this Contract.

1.2 INTERPRETIVE PROVISIONS

A. The meanings of defined terms include the singular and plural forms.
B. The words "hereof," "herein," "hereunder," and similar words refer to this Contract as a whole and not to any particular provision, section, Attachment, or schedule of this Contract unless otherwise specified.
C. The term "including" is not limiting and means "including without limitation" and, unless otherwise expressly provided in this Contract, (i) references to contracts (including this Contract) and other contractual instruments shall be deemed to include all subsequent Amendments and other modifications, but only to the extent that such Amendments and other modifications are not prohibited by the terms of this Contract, and (ii) references to any statute or regulation are to be construed as including all statutory and regulatory provisions consolidating, amending, replacing, supplementing, or interpreting the statute or regulation.
D. Any references to "sections," "appendices," or "attachments" are references to sections, appendices, or attachments of the Contract.
E. Any references to agreements, contracts, statutes, or administrative rules or regulations in the Contract are references to these documents as amended, modified, or supplemented from time to time during the term of the Contract.
F. The captions and headings of this Contract are for convenience of reference only and do not affect the interpretation of this Contract.
G. All Attachments, including those incorporated by reference, and any Amendments are considered part of the terms of this Contract.
H. This Contract may use several different limitations, regulations, or policies to regulate the same or similar matters. All such limitations, regulations, and policies are cumulative and each will be performed in accordance with its terms.
I. Unless otherwise expressly provided, reference to any action of the System Agency or by the System Agency by way of consent, approval, or waiver will be deemed modified by the phrase "in its sole discretion."
J. Time is of the essence in this Contract.

ARTICLE II. PAYMENT PROVISIONS

2.1 PROMPT PAYMENT

Payment shall be made in accordance with Chapter 2251 of the Texas Government Code, commonly known as the Texas Prompt Payment Act. Chapter 2251 of the Texas Government Code shall govern remittance of payment and remedies for late payment and non-payment.

2.2 ANCILLARY AND TRAVEL EXPENSES

A. Except as otherwise provided in the Contract, no ancillary expenses incurred by the Contractor in connection with its provision of the Services or Deliverables will be reimbursed by the System Agency. Ancillary expenses include, but are not limited to costs associated with transportation, delivery, and insurance for each Deliverable.

B. When the reimbursement of travel expenses is authorized by the Contract, all such expenses will be reimbursed in accordance with the rates set by the State of Texas *Textravel* available at the Texas Comptroller of Public Accounts State Travel Management Program website.

2.3 NO QUANTITY GUARANTEES

The System Agency makes no guarantee of volume or usage of work under this Contract. All Work requested may be on an irregular and as needed basis throughout the Contract term.

2.4 TAXES

Purchases made for State of Texas use are exempt from the State Sales Tax and Federal Excise Tax. Contractor represents and warrants that it shall pay all taxes or similar amounts resulting from the Contract, including, but not limited to, any federal, State, or local income, sales or excise taxes of Contractor or its employees. System Agency shall not be liable for any taxes resulting from the contract.

ARTICLE III. STATE AND FEDERAL FUNDING

3.1 EXCESS OBLIGATIONS PROHIBITED

The Contract is subject to termination or cancellation, without penalty to the System Agency, ether in whole or in part, subject to the availability of state funds. System Agency is a state agency whose authority and appropriations are subject to actions of the Texas Legislature. If System Agency becomes subject to a legislative change, revocation of statutory authority, or lack of appropriated funds that would render either System Agency's or Contractor's delivery or performance under the Contract impossible or unnecessary, the Contract will be terminated or cancelled and be deemed null and void. In the event of a termination or cancellation under this Section, System Agency will not be liable to Contractor for any damages that are caused or associated with such termination, or cancellation, and System Agency will not be required to give prior notice.

3.2 NO DEBT AGAINST THE STATE

This Contract will not be construed as creating any debt by or on behalf of the State of Texas.

3.3 DEBT AND DELINQUENCIES

Contractor agrees that any payments due under the Contract shall be directly applied towards eliminating any debt or delinquency it has to the State of Texas including, but not limited to, delinquent taxes, delinquent student loan payments, and delinquent child support.

3.4 REFUNDS AND OVERPAYMENTS

A . At its sole discretion, the System Agency may:
  i.   withhold all or part of any payments to Contractor to offset overpayments, unallowable or ineligible costs made to the Contractor, or if any required financial status report(s) is not submitted by the due date(s); or,
  ii. require Contractor to promptly refund or credit - within thirty (30) calendar days of written notice - any funds erroneously paid by System Agency which are not expressly authorized under the Contract.
B. "Overpayments," as used in this Section, include payments:
  i.   made by the System Agency that exceed the maximum allowable rates;
  ii. that are not allowed under applicable laws, rules, or regulations; or,
  iii. that are otherwise inconsistent with this Contract, including any unapproved expenditures. Contractor understands and agrees that it will be liable to the System Agency for any costs disallowed pursuant to financial and compliance audit(s) of funds received under this Contract. Contractor further understands and agrees that reimbursement of such disallowed costs shall be paid by Contractor from funds which were not provided or otherwise made available to Contractor under this Contract.

ARTICLE IV. WARRANTY, AFFIRMATIONS, ASSURANCES, AND CERTIFICATIONS

4.1 WARRANTY

Contractor warrants that all Work under this Contract shall be completed in a manner consistent with standards under the terms of this Contract, in the applicable trade, profession, or industry; shall conform to or exceed the specifications set forth in the Contract; and all Deliverables shall be fit for ordinary use, of good quality, and with no material defects. If System Agency, in its sole discretion, determines Contractor has failed to complete Work timely or to perform satisfactorily under conditions required by this Contract, the System Agency may require Contractor, at its sole expense, to:
  i.   Repair or replace all defective or damaged Work;
  ii. Refund any payment Contractor received from System Agency for all defective or damaged Work and, in conjunction therewith, require Contractor to accept the return of such Work; and,
  iii. Take necessary action to ensure that Contractor's future performance and Work conform to the Contract requirements.

4.2 GENERAL AFFIRMATIONS

Contractor certifies that, to the extent General Affirmations are incorporated into the Contract under the Signature Document, the Contractor has reviewed the General Affirmations and that Contractor is in compliance with all requirements.

4.3 FEDERAL ASSURANCES

Contractor certifies that, to the extent federal assurances are incorporated into the Contract under the Signature Document, the Contractor has reviewed the federal assurances and that Contractor is in compliance with all requirements.

4.4 FEDERAL CERTIFICATIONS

Contractor certifies that, to the extent federal certifications are incorporated into the Contract under the Signature Document, the Contractor has reviewed the federal certifications and that Contractor is in compliance with all requirements. In addition, Contractor certifies that it is and shall remain in compliance with all applicable federal laws, rules, and regulations, as they may pertain to this Contract.

ARTICLE V. INTELLECTUAL PROPERTY

5.1 OWNERSHIP OF WORK PRODUCT

A. All right, title, and interest in the Work Product, including all Intellectual Property Rights therein, is exclusively owned by System Agency. Contractor and Contractor's employees will have no rights in or ownership of the Work Product or any other property of System Agency.

B. Any and all Work Product that is copyrightable under United States copyright law is deemed to be "work made for hire" owned by System Agency, as provided by Title 17 of the United States Code. To the extent that Work Product does not qualify as a "work made for hire" under applicable federal law, Contractor hereby irrevocably assigns and transfers to System Agency, its successors and assigns, the entire right, title, and interest in and to the Work Product, including any and all Intellectual Property Rights embodied therein or associated therewith, and in and to all works based upon, derived from, or incorporating the Work Product, and in and to all income, royalties, damages, claims and payments now or hereafter due or payable with respect thereto, and in and to all causes of action, either in law or in equity for past, present or future infringement based on the copyrights, and in and to all rights corresponding to the foregoing.

C. Contractor agrees to execute all papers and to perform such other acts as System Agency may deem necessary to secure for System Agency or its designee the rights herein assigned.

D. In the event that Contractor has any rights in and to the Work Product that cannot be assigned to System Agency, Contractor hereby grants to System Agency an exclusive, worldwide, royalty-free, transferable, irrevocable, and perpetual license, with the right to sublicense, to reproduce, distribute, modify, create derivative works of, publicly perform and publicly display, make, have made, use, sell and offer for sale the Work Product and any products developed by practicing such rights.

E. The foregoing does not apply to Incorporated Pre-existing Works or Third Party IP that are incorporated in the Work Product by Contractor. Contractor shall provide System Agency access during normal business hours to all Vendor materials, premises, and computer files containing the Work Product.

5.2 CONTRACTOR'S PRE-EXISTING WORKS

A. To the extent that Contractor incorporates into the Work Product any works of Contractor that were created by Contractor or that Contractor acquired rights in prior to the Effective

Date of this Contract ("**Incorporated Pre-existing Works**"), Contractor retains ownership of such Incorporated Pre-existing Works.

B. Contractor hereby grants to System Agency an irrevocable, perpetual, non-exclusive, royalty-free, transferable, worldwide right and license, with the right to sublicense, to use, reproduce, modify, copy, create derivative works of, publish, publicly perform and display, sell, offer to sell, make and have made, the Incorporated Pre-existing Works, in any medium, with or without the associated Work Product.

C. Contractor represents, warrants, and covenants to System Agency that Contractor has all necessary right and authority to grant the foregoing license in the Incorporated Pre-existing Works to System Agency.

5.3 THIRD PARTY IP

A. To the extent that any Third Party IP is included or incorporated in the Work Product by Contractor, Contractor hereby grants to System Agency, or shall obtain from the applicable third party for System Agency's benefit, the irrevocable, perpetual, non-exclusive, worldwide, royalty-free right and license, for System Agency's internal business purposes only,

   i. to use, reproduce, display, perform, distribute copies of, and prepare derivative works based upon such Third Party IP and any derivative works thereof embodied in or delivered to System Agency in conjunction with the Work Product, and

   ii. to authorize others to do any or all of the foregoing.

B. Contractor shall obtain System Agency's advance written approval prior to incorporating any Third Party IP into the Work Product, and Contractor shall notify System Agency on delivery of the Work Product if such materials include any Third Party IP.

C. Contractor shall provide System Agency all supporting documentation demonstrating Contractor's compliance with this **Section 5.3**, including without limitation documentation indicating a third party's written approval for Contractor to use any Third Party IP that may be incorporated in the Work Product.

5.4 AGREEMENTS WITH EMPLOYEES AND SUBCONTRACTORS

Contractor shall have written, binding agreements with its employees and subcontractors that include provisions sufficient to give effect to and enable Contractor's compliance with Contractor's obligations under this **Article V**.

5.5 DELIVERY UPON TERMINATION OR EXPIRATION

No later than the first calendar day after the termination or expiration of the Contract or upon System Agency's request, Contractor shall deliver to System Agency all completed, or partially completed, Work Product, including any Incorporated Pre-existing Works, and any and all versions thereof. Contractor's failure to timely deliver such Work Product is a material breach of the Contract. Contractor will not retain any copies of the Work Product or any documentation or other products or results of Contractor's activities under the Contract without the prior written consent of System Agency.

5.6 SURVIVAL

The provisions and obligations of this **Article V** survive any termination or expiration of the Contract.

5.7 SYSTEM AGENCY DATA

A. As between the Parties, all data and information acquired, accessed, or made available to Contractor by, through, or on behalf of System Agency or System Agency contractors, including all electronic data generated, processed, transmitted, or stored by Contractor in the course of providing data processing services in connection with Contractor's performance hereunder (the "**System Agency Data**"), is owned solely by System Agency.

B. Contractor has no right or license to use, analyze, aggregate, transmit, create derivatives of, copy, disclose, or process the System Agency Data except as required for Contractor to fulfill its obligations under the Contract or as authorized in advance in writing by System Agency.

C. For the avoidance of doubt, Contractor is expressly prohibited from using, and from permitting any third party to use, System Agency Data for marketing, research, or other non-governmental or commercial purposes, without the prior written consent of System Agency.

D. Contractor shall make System Agency Data available to System Agency, including to System Agency's designated vendors, as directed in writing by System Agency. The foregoing shall be at no cost to System Agency.

E. Furthermore, the proprietary nature of Contractor's systems that process, store, collect, and/or transmit the System Agency Data shall not excuse Contractor's performance of its obligations hereunder.

ARTICLE VI. PROPERTY

6.1 USE OF STATE PROPERTY

A. Contractor is prohibited from using State Property for any purpose other than performing Services authorized under the Contract.

B. State Property includes, but is not limited to, System Agency's office space, identification badges, System Agency information technology equipment and networks (*e.g.,* laptops, portable printers, cell phones, iPads or tablets, external hard drives, data storage devices, any System Agency-issued software, and the System Agency Virtual Private Network (VPN client)), and any other resources of System Agency.

C. Contractor shall not remove State Property from the continental United States. In addition, Contractor may not use any computing device to access System Agency's network or e-mail while outside of the continental United States.

D. Contractor shall not perform any maintenance services on State Property unless the Contract expressly authorizes such Services.

E. During the time that State Property is in the possession of Contractor, Contractor shall be responsible for:

    i. all repair and replacement charges incurred by State Agency that are associated with loss of State Property or damage beyond normal wear and tear, and

    ii. all charges attributable to Contractor's use of State Property that exceeds the Contract scope. Contractor shall fully reimburse such charges to System Agency within ten (10) calendar days of Contractor's receipt of System Agency's notice of amount due. Use of State Property for a purpose not authorized by the Contract shall constitute breach of contract and may result in termination of the Contract and the pursuit of other remedies available to System Agency under contract, at law, or in equity.

6.2 DAMAGE TO GOVERNMENT PROPERTY

A. In the event of loss, destruction, or damage to any System Agency or State of Texas owned, leased, or occupied property or equipment by Contractor or Contractor's employees, agents, Subcontractors, and suppliers, Contractor shall be liable to System Agency and the State of Texas for the full cost of repair, reconstruction, or replacement of the lost, destroyed, or damaged property.

B. Contractor shall notify System Agency of the loss, destruction, or damage of equipment or property within one (1) business day. Contractor shall reimburse System Agency and the State of Texas for such property damage within 10 calendar days after Contractor's receipt of System Agency's notice of amount due.

6.3 PROPERTY RIGHTS UPON TERMINATION OR EXPIRATION OF CONTRACT

In the event the Contract is terminated for any reason, or upon its expiration State Property remains the property of the System Agency and must be returned to the System Agency by the end date of the Contract or upon System Agency's request.

ARTICLE VII. WORK ORDERS

7.1 WORK ORDERS

If the Contract is for indefinite quantities of Services, as specified in the Signature Document, all Work will be performed in accordance with properly executed Work Orders.

7.2 PROPOSALS

For Work Order contracts, the Contractor shall submit to System Agency separate proposals, including pricing and a project plan, for each Project.

7.3 RESPONSIBILITY

For each approved Project, the Contractor shall be responsible for all Work assigned under the Work Order. Multiple Work Orders may be issued during the term of this Contract, all of which will be in writing and signed by the Parties. Each Work Order will include a scope of Services; a list of tasks required; a time schedule; a list of Deliverables, if any; a detailed Project budget; and any other information or special conditions as may be necessary for the Work assigned.

7.4 TERMINATION

If this Work Order is in effect on the day the Contract would otherwise expire, the Contract will remain in effect until this Work Order is terminated or expires; and the Contract and this Work Order may be amended after such termination or expiration to extend the performance period or add ancillary deliverables or services, only to the extent necessary.

ARTICLE VIII. RECORD RETENTION, AUDIT, AND CONFIDENTIALITY

8.1 RECORD MAINTENANCE AND RETENTION

A. Contractor shall keep and maintain under GAAP or GASB, as applicable, full, true, and complete records necessary to fully disclose to the System Agency, the Texas State Auditor's Office, the United States Government, and their authorized representatives

sufficient information to determine compliance with the terms and conditions of this Contract and all state and federal rules, regulations, and statutes.

B. Contractor shall maintain and retain legible copies of this Contract and all records relating to the performance of the Contract including supporting fiscal documents adequate to ensure that claims for contract funds are in accordance with applicable State of Texas requirements. These records shall be maintained and retained by Contractor for a minimum of seven (7) years after the Contract expiration date or seven (7) years after the completion of all audit, claim, litigation, or dispute matters involving the Contract are resolved, whichever is later.

8.2 AGENCY'S RIGHT TO AUDIT

A. Contractor shall make available at reasonable times and upon reasonable notice, and for reasonable periods, work papers, reports, books, records, supporting documents kept current by Contractor pertaining to the Contract for purposes of inspecting, monitoring, auditing, or evaluating by System Agency and the State of Texas.

B. In addition to any right of access arising by operation of law, Contractor and any of Contractor's affiliate or subsidiary organizations, or Subcontractors shall permit the System Agency or any of its duly authorized representatives, as well as duly authorized federal, state or local authorities, unrestricted access to and the right to examine any site where business is conducted or Services are performed, and all records, which includes but is not limited to financial, client and patient records, books, papers or documents related to this Contract. If the Contract includes federal funds, federal agencies that shall have a right of access to records as described in this section include: the federal agency providing the funds, the Comptroller General of the United States, the General Accounting Office, the Office of the Inspector General, and any of their authorized representatives. In addition, agencies of the State of Texas that shall have a right of access to records as described in this section include: the System Agency, HHSC, HHSC's contracted examiners, the State Auditor's Office, the Texas Attorney General's Office, and any successor agencies. Each of these entities may be a duly authorized authority.

C. If deemed necessary by the System Agency or any duly authorized authority, for the purpose of investigation or hearing, Contractor shall produce original documents related to this Contract.

D. The System Agency and any duly authorized authority shall have the right to audit billings both before and after payment, and all documentation that substantiates the billings.

E. Contractor shall include this provision concerning the right of access to, and examination of, sites and information related to this Contract in any Subcontract it awards.

8.3 RESPONSE/COMPLIANCE WITH AUDIT OR INSPECTION FINDINGS

A. Contractor must act to ensure its and its Subcontractors' compliance with all corrections necessary to address any finding of noncompliance with any law, regulation, audit requirement, or generally accepted accounting principle, or any other deficiency identified in any audit, review, or inspection of the Contract and the Services and Deliverables provided. Any such correction will be at Contractor's or its Subcontractor's sole expense. Whether Contractor's action corrects the noncompliance shall be solely the decision of the System Agency.

B. As part of the Services, Contractor must provide to System Agency upon request a copy of those portions of Contractor's and its Subcontractors' internal audit reports relating to the Services and Deliverables provided to the State under the Contract.

8.4 STATE AUDITOR'S RIGHT TO AUDIT

A. The state auditor may conduct an audit or investigation of any entity receiving funds from the state directly under the Contract or indirectly through a subcontract under the Contract. The acceptance of funds directly under the Contract or indirectly through a subcontract under the Contract acts as acceptance of the authority of the state auditor, under the direction of the legislative audit committee, to conduct an audit or investigation in connection with those funds. Under the direction of the legislative audit committee, an entity that is the subject of an audit or investigation by the state auditor must provide the state auditor with access to any information the state auditor considers relevant to the investigation or audit.

B. The Contractor shall comply with any rules and procedures of the state auditor in the implementation and enforcement of Section 2262.154 of the Texas Government Code.

8.5 CONFIDENTIALITY

Contractor shall maintain as confidential and shall not disclose to third parties without System Agency's prior written consent, any System Agency information including but not limited to System Agency Data, System Agency's business activities, practices, systems, conditions and services. This section will survive termination or expiration of this Contract. The obligations of Contractor under this section will survive termination or expiration of this Contract. This requirement must be included in all subcontracts awarded by Contractor.

ARTICLE IX. CONTRACT REMEDIES AND EARLY TERMINATION

9.1 CONTRACT REMEDIES

To ensure Contractor's full performance of the Contract and compliance with applicable law, the System Agency reserves the right to hold Contractor accountable for breach of contract or substandard performance and may take remedial or corrective actions, including, but not limited to:
    i. suspending all or part of the Contract;
   ii. requiring the Contractor to take specific actions in order to remain in compliance with the Contract;
  iii. recouping payments made by the System Agency to the Contractor found to be in error;
   iv. suspending, limiting, or placing conditions on the Contractor's continued performance of Work; or
    v. imposing any other remedies, sanctions, or penalties authorized under this Contract or permitted by federal or state law.

9.2 TERMINATION FOR CONVENIENCE

The System Agency may terminate the Contract, in whole or in part, at any time when, in its sole discretion, the System Agency determines that termination is in the best interests of

the State of Texas. The termination will be effective on the date specified in the System Agency's notice of termination.

9.3 TERMINATION FOR CAUSE

Except as otherwise provided by the U.S. Bankruptcy Code, or any successor law, the System Agency may terminate the Contract, in whole or in part, upon either of the following conditions:

i. Material Breach
The System Agency will have the right to terminate the Contract in whole or in part if the System Agency determines, in its sole discretion, that Contractor has materially breached the Contract or has failed to adhere to any laws, ordinances, rules, regulations or orders of any public authority having jurisdiction and such violation prevents or substantially impairs performance of Contractor's duties under the Contract. Contractor's misrepresentation in any aspect of Contractor's Solicitation Response, if any, or Contractor's addition to the System for Award Management (SAM) will also constitute a material breach of the Contract.

ii. Failure to Maintain Financial Viability
The System Agency may terminate the Contract if, in its sole discretion, the System Agency has a good faith belief that Contractor no longer maintains the financial viability required to complete the Work, or otherwise fully perform its responsibilities under the Contract.

9.4 CONTRACTOR RESPONSIBILITY FOR SYSTEM AGENCY'S TERMINATION COSTS

If the System Agency terminates the Contract for cause, the Contractor shall be responsible to the System Agency for all costs incurred by the System Agency and the State of Texas to replace the Contractor. These costs include, but are not limited to, the costs of procuring a substitute vendor and the cost of any claim or litigation attributable to Contractor's failure to perform any Work in accordance with the terms of the Contract.

ARTICLE X. INDEMNITY

10.1 GENERAL INDEMNITY

A. CONTRACTOR SHALL DEFEND, INDEMNIFY AND HOLD HARMLESS THE STATE OF TEXAS AND SYSTEM AGENCY, AND/OR THEIR OFFICERS, AGENTS, EMPLOYEES, REPRESENTATIVES, CONTRACTORS, ASSIGNEES, AND/OR DESIGNEES FROM ANY AND ALL LIABILITY, ACTIONS, CLAIMS, DEMANDS, OR SUITS, AND ALL RELATED COSTS, ATTORNEY FEES, AND EXPENSES ARISING OUT OF OR RESULTING FROM ANY ACTS OR OMISSIONS OF CONTRACTOR OR ITS AGENTS, EMPLOYEES, SUBCONTRACTORS, ORDER FULFILLERS, OR SUPPLIERS OF SUBCONTRACTORS IN THE EXECUTION OR PERFORMANCE OF THE CONTRACT AND ANY PURCHASE ORDERS ISSUED UNDER THE CONTRACT.

B. THIS PARAGRAPH IS NOT INTENDED TO AND WILL NOT BE CONSTRUED TO REQUIRE CONTRACTOR TO INDEMNIFY OR HOLD HARMLESS THE STATE OR THE SYSTEM AGENCY FOR ANY CLAIMS OR LIABILITIES

RESULTING FROM THE NEGLIGENT ACTS OF OMISSIONS OF THE SYSTEM AGENCY OR ITS EMPLOYEES.

C. For the avoidance of doubt, System Agency shall not indemnify Contractor or any other entity under the Contract.

10.2 INTELLECTUAL PROPERTY

CONTRACTOR SHALL DEFEND, INDEMNIFY, AND HOLD HARMLESS THE SYSTEM AGENCY AND THE STATE OF TEXAS FROM AND AGAINST ANY AND ALL CLAIMS, VIOLATIONS, MISAPPROPRIATIONS, OR INFRINGEMENT OF ANY PATENT, TRADEMARK, COPYRIGHT, TRADE SECRET, OR OTHER INTELLECTUAL PROPERTY RIGHTS AND/OR OTHER INTANGIBLE PROPERTY, PUBLICITY OR PRIVACY RIGHTS, AND/OR IN CONNECTION WITH OR ARISING FROM:

i. THE PERFORMANCE OR ACTIONS OF CONTRACTOR PURSUANT TO THIS CONTRACT;

ii. ANY DELIVERABLE, WORK PRODUCT, CONFIGURED SERVICE OR OTHER SERVICE PROVIDED HEREUNDER; AND/OR

iii. SYSTEM AGENCY'S AND/OR CONTRACTOR'S USE OF OR ACQUISITION OF ANY REQUESTED SERVICES OR OTHER ITEMS PROVIDED TO SYSTEM AGENCY BY CONTRACTOR OR OTHERWISE TO WHICH SYSTEM AGENCY HAS ACCESS AS A RESULT OF CONTRACTOR'S PERFORMANCE UNDER THE CONTRACT.

10.3 ADDITIONAL INDEMNITY PROVISIONS

A. CONTRACTOR AND SYSTEM AGENCY AGREE TO FURNISH TIMELY WRITTEN NOTICE TO EACH OTHER OF ANY INDEMNITY CLAIM. CONTRACTOR SHALL BE LIABLE TO PAY ALL COSTS OF DEFENSE, INCLUDING ATTORNEYS' FEES.

B. THE DEFENSE SHALL BE COORDINATED BY THE CONTRACTOR WITH THE OFFICE OF THE TEXAS ATTORNEY GENERAL WHEN TEXAS STATE AGENCIES ARE NAMED DEFENDANTS IN ANY LAWSUIT AND CONTRACTOR MAY NOT AGREE TO ANY SETTLEMENT WITHOUT FIRST OBTAINING THE CONCURRENCE FROM THE OFFICE OF THE TEXAS ATTORNEY GENERAL.

C. CONTRACTOR SHALL REIMBURSE SYSTEM AGENCY AND THE STATE OF TEXAS FOR ANY CLAIMS, DAMAGES, COSTS, EXPENSES OR OTHER AMOUNTS, INCLUDING, BUT NOT LIMITED TO, ATTORNEYS' FEES AND COURT COSTS, ARISING FROM ANY SUCH CLAIM. IF THE SYSTEM AGENCY DETERMINES THAT A CONFLICT EXISTS BETWEEN ITS INTERESTS AND THOSE OF CONTRACTOR OR IF SYSTEM AGENCY IS REQUIRED BY APPLICABLE LAW TO SELECT SEPARATE COUNSEL, SYSTEM AGENCY WILL BE PERMITTED TO SELECT SEPARATE COUNSEL AND CONTRACTOR SHALL PAY ALL REASONABLE COSTS OF SYSTEM AGENCY'S COUNSEL.

ARTICLE XI. GENERAL PROVISIONS

11.1 AMENDMENT

The Contract may only be amended by an Amendment executed by both Parties.

11.2 INSURANCE

A. Unless otherwise specified in this Contract, Contractor shall acquire and maintain, for the duration of this Contract, insurance coverage necessary to ensure proper fulfillment of this Contract and potential liabilities thereunder with financially sound and reputable insurers licensed by the Texas Department of Insurance, in the type and amount customarily carried within the industry as determined by the System Agency. Contractor shall provide evidence of insurance as required under this Contract, including a schedule of coverage or underwriter's schedules establishing to the satisfaction of the System Agency the nature and extent of coverage granted by each such policy, upon request by the System Agency. In the event that any policy is determined by the System Agency to be deficient to comply with the terms of this Contract, Contractor shall secure such additional policies or coverage as the System Agency may reasonably request or that are required by law or regulation. If coverage expires during the term of this Contract, Contractor must produce renewal certificates for each type of coverage.

B. These and all other insurance requirements under the Contract apply to both Contractor and its Subcontractors, if any. Contractor is responsible for ensuring its Subcontractors' compliance with all requirements.

11.3 LIMITATION ON AUTHORITY

A. The authority granted to Contractor by the System Agency is limited to the terms of the Contract.

B. Contractor shall not have any authority to act for or on behalf of the System Agency or the State of Texas except as expressly provided for in the Contract; no other authority, power, or use is granted or implied. Contractor may not incur any debt, obligation, expense, or liability of any kind on behalf of System Agency or the State of Texas.

C. Contractor may not rely upon implied authority and is not granted authority under the Contract to:
   i. Make public policy on behalf of the System Agency;
   ii. Promulgate, amend, or disregard administrative regulations or program policy decisions made by State and federal agencies responsible for administration of a System Agency program; or
   iii. Unilaterally communicate or negotiate with any federal or state agency or the Texas Legislature on behalf of the System Agency regarding System Agency programs or the Contract. However, upon System Agency request and with reasonable notice from System Agency to the Contractor, the Contractor shall assist the System Agency in communications and negotiations regarding the Work under the Contract with state and federal governments.

11.4 LEGAL OBLIGATIONS

Contractor shall comply with all applicable federal, state, and local laws, ordinances, and regulations, including all federal and state accessibility laws relating to direct and indirect use

of information and communication technology. Contractor shall be deemed to have knowledge of all applicable laws and regulations and be deemed to understand them.

11.5 CHANGE IN LAWS AND COMPLIANCE WITH LAWS

Contractor shall comply with all laws, regulations, requirements and guidelines applicable to a vendor providing services and products required by the Contract to the State of Texas, as these laws, regulations, requirements and guidelines currently exist and as amended throughout the term of the Contract. System Agency reserves the right, in its sole discretion, to unilaterally amend the Contract to incorporate any modifications necessary for System Agency's compliance, as an agency of the State of Texas, with all applicable state and federal laws, regulations, requirements and guidelines.

11.6 E-VERIFY PROGRAM

Contractor certifies that for Contracts for Services, Contractor shall utilize the U.S. Department of Homeland Security's E-Verify system during the term of the Contract to determine the eligibility of:
  i. all persons employed by Contractor to perform duties within Texas; and
  ii. all persons, including subcontractors, assigned by the Contractor to perform Work pursuant to the Contract within the United States of America.

11.7 PERMITTING AND LICENSURE

At Contractor's sole expense, Contractor shall procure and maintain for the duration of this Contract any state, county, city, or federal license, authorization, insurance, waiver, permit, qualification or certification required by statute, ordinance, law, or regulation to be held by Contractor to provide the goods or Services required by this Contract. Contractor shall be responsible for payment of all taxes, assessments, fees, premiums, permits, and licenses required by law. Contractor shall be responsible for payment of any such government obligations not paid by its Subcontractors during performance of this Contract.

11.8 SUBCONTRACTORS

Contractor may not subcontract any or all of the Work and/or obligations under the Contract without prior written approval of the System Agency. Subcontracts, if any, entered into by the Contractor shall be in writing and be subject to the requirements of the Contract. Should Contractor Subcontract any of the services required in the Contract, Contractor expressly understands and acknowledges that in entering into such Subcontract(s), System Agency is in no manner liable to any subcontractor(s) of Contractor. In no event shall this provision relieve Contractor of the responsibility for ensuring that the services performed under all Subcontracts are rendered in compliance with the Contract.

11.9 INDEPENDENT CONTRACTOR

Contractor and Contractor's employees, representatives, agents, Subcontractors, suppliers, and third-party service providers shall serve as independent contractors in providing the services under the Contract. Neither Contractor nor System Agency is an agent of the other and neither may make any commitments on the other party's behalf. Contractor shall have no claim against System Agency for vacation pay, sick leave, retirement benefits, social security, worker's compensation, health or disability benefits, unemployment insurance benefits, or employee

benefits of any kind. The Contract shall not create any joint venture, partnership, agency, or employment relationship between Contractor and System Agency.

11.10 GOVERNING LAW AND VENUE

This Contract shall be governed by and construed in accordance with the laws of the State of Texas, without regard to the conflicts of law provisions. The venue of any suit arising under the Contract is fixed in any court of competent jurisdiction of Travis County, Texas, unless the specific venue is otherwise identified in a statute which directly names or otherwise identifies its applicability to the System Agency.

11.11 SEVERABILITY

If any provision of the Contract is held to be illegal, invalid or unenforceable by a court of law or equity, such construction will not affect the legality, validity or enforceability of any other provision or provisions of this Contract. It is the intent and agreement of the Parties this Contract shall be deemed amended by modifying such provision to the extent necessary to render it valid, legal and enforceable while preserving its intent or, if such modification is not possible, by substituting another provision that is valid, legal and enforceable and that achieves the same objective. All other provisions of this Contract will continue in full force and effect.

11.12 SURVIVABILITY

Expiration or termination of the Contract for any reason does not release Contractor from any liability or obligation set forth in the Contract that is expressly stated to survive any such expiration or termination, that by its nature would be intended to be applicable following any such expiration or termination, or that is necessary to fulfill the essential purpose of the Contract, including without limitation the provisions regarding warranty, indemnification, confidentiality, and rights and remedies upon termination.

11.13 FORCE MAJEURE

Neither Contractor nor System Agency shall be liable to the other for any delay in, or failure of performance of, any requirement included in the Contract caused by force majeure. The existence of such causes of delay or failure shall extend the period of performance until after the causes of delay or failure have been removed provided the non-performing party exercises all reasonable due diligence to perform. Force majeure is defined as acts of God, war, fires, explosions, hurricanes, floods, failure of transportation, or other causes that are beyond the reasonable control of either party and that by exercise of due foresight such party could not reasonably have been expected to avoid, and which, by the exercise of all reasonable due diligence, such party is unable to overcome.

11.14 DISPUTE RESOLUTION

A. The dispute resolution process provided for in Chapter 2260 of the Texas Government Code must be used to attempt to resolve any dispute arising under the Contract. If the Contractor's claim for breach of contract cannot be resolved informally with the System Agency, the claim shall be submitted to the negotiation process provided in Chapter 2260. To initiate the process, the Contractor shall submit written notice, as required by Chapter 2260, to the individual identified in the Contract for receipt of notices. Any informal resolution efforts shall in no way modify the requirements or toll the timing of the formal written notice of a claim for breach of contract required under §2260.051 of the Texas

Government Code. Compliance by the Contractor with Chapter 2260 is a condition precedent to the filing of a contested case proceeding under Chapter 2260.

B. The contested case process provided in Chapter 2260 is the Contractor's sole and exclusive process for seeking a remedy for an alleged breach of contract by the System Agency if the Parties are unable to resolve their disputes as described above.

C. Notwithstanding any other provision of the Contract to the contrary, unless otherwise requested or approved in writing by the System Agency, the Contractor shall continue performance and shall not be excused from performance during the period of any breach of contract claim or while the dispute is pending. However, the Contractor may suspend performance during the pendency of such claim or dispute if the Contractor has complied with all provisions of Section 2251.051, Texas Government Code, and such suspension of performance is expressly applicable and authorized under that law.

11.15 NO IMPLIED WAIVER OF PROVISIONS

The failure of the System Agency to object to or to take affirmative action with respect to any conduct of the Contractor which is in violation or breach of the terms of the Contract shall not be construed as a waiver of the violation or breach, or of any future violation or breach.

11.16 MEDIA RELEASES

A. Contractor shall not use System Agency's name, logo, or other likeness in any press release, marketing material, or other announcement without System Agency's prior written approval. System Agency does not endorse any vendor, commodity, or service. Contractor is not authorized to make or participate in any media releases or public announcements pertaining to this Contract or the Services to which they relate without System Agency's prior written consent, and then only in accordance with explicit written instruction from System Agency.

B. Contractor may publish, at its sole expense, results of Contractor performance under the Contract with the System Agency's prior review and approval, which the System Agency may exercise at its sole discretion. Any publication (written, visual, or sound) will acknowledge the support received from the System Agency and any Federal agency, as appropriate.

11.17 NO MARKETING ACTIVITIES

Contractor is prohibited from using the Work for any Contractor or third-party marketing, advertising, or promotional activities, without the prior written consent of System Agency. The foregoing prohibition includes, without limitation, the placement of banners, pop-up ads, or other advertisements promoting Contractor's or a third party's products, services, workshops, trainings, or other commercial offerings on any website portal or internet-based service or software application hosted or managed by Contractor as part of the Work.

11.18 PROHIBITION ON NON-COMPETE RESTRICTIONS

Contractor shall not require any employees or Subcontractors to agree to any conditions, such as non-compete clauses or other contractual arrangements that would limit or restrict such persons or entities from employment or contracting with the State of Texas.

11.19 SOVEREIGN IMMUNITY

Nothing in the Contract shall be construed as a waiver of the System Agency's or the State's sovereign immunity. This Contract shall not constitute or be construed as a waiver of any of the privileges, rights, defenses, remedies, or immunities available to the System Agency or the State of Texas. The failure to enforce, or any delay in the enforcement of, any privileges, rights, defenses, remedies, or immunities available to the System Agency or the State of Texas under the Contract or under applicable law shall not constitute a waiver of such privileges, rights, defenses, remedies, or immunities or be considered as a basis for estoppel. System Agency does not waive any privileges, rights, defenses, or immunities available to System Agency by entering into the Contract or by its conduct prior to or subsequent to entering into the Contract.

11.20 ENTIRE CONTRACT AND MODIFICATION

This Contract constitutes the entire agreement of the Parties and is intended as a complete and exclusive statement of the promises, representations, negotiations, discussions, and other agreements that may have been made in connection with the subject matter hereof. Any additional or conflicting terms in any future document incorporated into the Contract will be harmonized with this Contract to the extent possible.

11.21 COUNTERPARTS

This Contract may be executed in any number of counterparts, each of which will be an original, and all such counterparts will together constitute but one and the same Contract.

11.22 CIVIL RIGHTS

A. Contractor shall comply with all applicable state and federal anti-discrimination laws, including:

   i. Title VI of the Civil Rights Act of 1964 (42 U.S.C. §2000d, *et seq.*);
   ii. Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. §794);
   iii. Americans with Disabilities Act of 1990 (42 U.S.C. §12101, *et seq.*);
   iv. Age Discrimination Act of 1975 (42 U.S.C. §6101, *et seq.*);
   v. Title IX of the Education Amendments of 1972 (20 U.S.C. §1681, *et seq.*);
   vi. Food and Nutrition Act of 2008 (7 U.S.C. §2011, *et seq.*); and
   vii. The System Agency's administrative rules, as set forth in the Texas Administrative Code, to the extent applicable to this Agreement.

B. Contractor shall comply with all amendments to these laws, and all requirements imposed by the regulations issued pursuant to these laws. These laws provide in part that no persons in the United States may, on the grounds of race, color, national origin, sex, age, disability, political beliefs, or religion, be excluded from participation in or denied any service or other benefit provided by Federal or State funding, or otherwise be subjected to discrimination.

C. Contractor shall comply with Title VI of the Civil Rights Act of 1964, and its implementing regulations at 45 C.F.R. Part 80 or 7 C.F.R. Part 15, prohibiting a contractor from adopting and implementing policies and procedures that exclude or have the effect of excluding or limiting the participation of clients in its programs, benefits, or activities on the basis of national origin. Civil rights laws require contractors to provide alternative methods for ensuring access to services for applicants and recipients who cannot express themselves fluently in English. Contractor shall take reasonable steps to provide services

and information, both orally and in writing and electronically, in appropriate languages other than English, to ensure that persons with limited English proficiency are effectively informed and can have meaningful access to programs, benefits, and activities.

Contractor shall post applicable civil rights posters in areas open to the public informing clients of their civil rights and including contact information for the HHS Civil Rights Office. The posters are available on the HHS website at:
http://hhscx.hhsc.texas.gov/system-support-services/civil-rights/publications

D. Contractor shall comply with Section 504 of the Rehabilitation Act of 1973 and its implementing regulations at 28 CFR Subpart G § 42.503, and Americans with Disabilities Act of 1990 and its implementing regulations at 28 CFR Subpart B §35.130 which includes requiring contractor to make reasonable modifications in policies, practices, or procedures when the modifications are necessary to avoid discrimination on the basis of disability, unless the contractor can demonstrate that making the modifications would fundamentally alter the nature of the service, program, or activity.

E. Contractor shall comply with federal regulations regarding equal treatment for faith-based organizations under 45 C.F.R. Part 87 or 7 C.F.R. Part 16, as applicable. Contractor shall not discriminate against clients or prospective clients on the basis of religion or religious belief, and shall provide written notice to beneficiaries of their rights.

F. Upon request, Contractor shall provide the HHSC Civil Rights Office with copies of the Contractor's civil rights policies and procedures.

G. Contractor must notify HHSC's Civil Rights Office of any civil rights complaints received relating to its performance under this Contract. This notice must be delivered no more than ten (10) calendar days after receipt of a complaint. This notice must be directed to:

HHSC Civil Rights Office
701 W. 51st Street, Mail Code W206
Austin, Texas 78751
Phone Toll Free: (888) 388-6332
Phone: (512) 438-4313
Fax: (512) 438-5885.

11.23 ENTERPRISE INFORMATION MANAGEMENT STANDARDS

Contractor shall conform to HHS standards for data management as described by the policies of the HHS Chief Data and Analytics Officer. These include, but are not limited to, standards for documentation and communication of data models, metadata, and other data definition methods that are required by HHS for ongoing data governance, strategic portfolio analysis, interoperability planning, and valuation of HHS System data assets.

11.24 DISCLOSURE OF LITIGATION

A. The Contractor must disclose in writing to the contract manager assigned to this Contract any material civil or criminal litigation or indictment either threatened or pending involving the Contractor. "Threatened litigation" as used herein shall include governmental investigations and civil investigative demands. "Litigation" as used herein shall include administrative enforcement actions brought by governmental agencies. The Contractor must also disclose any material litigation threatened or pending involving Subcontractors, consultants, and/or lobbyists. For purposes of this section, "material" refers, but is not limited, to any action or pending action that a reasonable person knowledgeable in the applicable industry would consider relevant to the Work under the Contract or any

development such a person would want to be aware of in order to stay fully apprised of the total mix of information relevant to the Work, together with any litigation threatened or pending that may result in a substantial change in the Contractor's financial condition.

B. This is a continuing disclosure requirement; any litigation commencing after Contract Award must be disclosed in a written statement to the assigned contract manager within seven calendar days of its occurrence.

11.25 NO THIRD-PARTY BENEFICIARIES

The Contract is made solely and specifically among and for the benefit of the Parties named herein and their respective successors and assigns, and no other person shall have any right, interest, or claims hereunder or be entitled to any benefits pursuant to or on account of the Contract as a third-party beneficiary or otherwise.

11.26 BINDING EFFECT

The Contract shall inure to the benefit of, be binding upon, and be enforceable against, each Party and their respective permitted successors, assigns, transferees, and delegates.

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HEALTH AND HUMAN SERVICES
CONTRACT AFFIRMATIONS

The term "System Agency" used in these affirmations means HHS or any of the agencies of the State of Texas that are overseen by HHSC under authority granted under Texas law and the officers, employees, authorized representatives, and designees of those agencies. These agencies include: HHSC and the Department of State Health Services.

By entering into this Contract, Contractor affirms, without exception, understands, and agrees to comply with the following items through the life of the Contract:

1. Contractor represents and warrants that these Contract Affirmations apply to Contractor and all of Contractor's principals, officers, directors, shareholders, partners, owners, agents, employees, subcontractors, independent contractors, and any other representatives who may provide services under, who have a financial interest in, or otherwise are interested in this Contract and any related Solicitation.

2. **Complete and Accurate Information**

   Contractor represents and warrants that all statements and information provided to System Agency are current, complete, and accurate. This includes all statements and information in this Contract and any related Solicitation Response.

3. **Public Information Act**

   Contractor understands that System Agency will comply with the Texas Public Information Act (Chapter 552 of the Texas Government Code) as interpreted by judicial rulings and opinions of the Attorney General of the State of Texas. Information, documentation, and other material prepared and submitted in connection with this Contract or any related Solicitation may be subject to public disclosure pursuant to the Texas Public Information Act. In accordance with Section 2252.907 of the Texas Government Code, Contractor is required to make any information created or exchanged with the State pursuant to the Contract, and not otherwise excepted from disclosure under the Texas Public Information Act, available in a format that is accessible by the public at no additional charge to the State.

4. **Contracting Information Requirements**

   Contractor represents and warrants that it will comply with the requirements of Section 552.372(a) of the Texas Government Code. Except as provided by Section 552.374(c) of the Texas Government Code, the requirements of Subchapter J (Additional Provisions Related to Contracting Information), Chapter 552 of the Government Code, may apply to the Contract and the Contractor agrees that the Contract can be terminated if the Contractor knowingly or intentionally fails to comply with a requirement of that subchapter.

5.   **Assignment**

    A. Contractor shall not assign its rights under the contract or delegate the performance of its duties under the contract without prior written approval from HHSC. Any attempted assignment in violation of this provision is void and without effect.

    B. Contractor understands and agrees the System Agency may in one or more transactions assign, pledge, or transfer the Contract. This assignment will only be made to another State agency or a non-state agency that is contracted to perform agency support. Upon receipt of System Agency's notice of assignment, pledge, or transfer, Contractor shall cooperate with System Agency in giving effect to such assignment, pledge, or transfer, at no cost to System Agency or to the recipient entity

6.   **Terms and Conditions Attached to Response**

Contractor accepts the Solicitation terms and conditions unless specifically noted by exceptions advanced in the form and manner directed in the Solicitation, if any, under which this Contract was awarded. Contractor agrees that all exceptions to the Solicitation, as well as terms and conditions advanced by Contractor that differ in any manner from System Agency's terms and conditions, if any, are rejected unless expressly accepted by System Agency in writing.

7.   **System Agency Right to Use**

Contractor agrees that System Agency has the right to use, produce, and distribute copies of and to disclose to System Agency employees, agents, and contractors and other governmental entities all or part of this Contract or any related Solicitation Response as System Agency deems necessary to complete the procurement process or comply with state or federal laws.

8.   **Release from Liability**

Contractor generally releases from liability and waives all claims against any party providing information about the Contractor at the request of System Agency.

9.   **Dealings with Public Servants**

Contractor has not given, has not offered to give, and does not intend to give at any time hereafter any economic opportunity, future employment, gift, loan, gratuity, special discount, trip, favor, or service to a public servant in connection with this Contract or any related Solicitation, or related Solicitation Response.

10. **Financial Participation Prohibited**

Under Section 2155.004, Texas Government Code (relating to financial participation in preparing solicitations), Contractor certifies that the individual or business entity named in this Contract and any related Solicitation Response is not ineligible to receive this Contract and acknowledges that this Contract may be terminated and payment withheld if this certification is inaccurate.

11.   **Prior Disaster Relief Contract Violation**

Under Sections 2155.006 and 2261.053 of the Texas Government Code (relating to convictions and penalties regarding Hurricane Rita, Hurricane Katrina, and other disasters), the Contractor certifies that the individual or business entity named in this Contract and any related Solicitation Response is not ineligible to receive this Contract and acknowledges that this Contract may be terminated and payment withheld if this certification is inaccurate.

12.   **Child Support Obligation**

Under Section 231.006(d) of the Texas Family Code regarding child support, Contractor certifies that the individual or business entity named in this Contract and any related Solicitation Response is not ineligible to receive the specified payment and acknowledges that the Contract may be terminated and payment may be withheld if this certification is inaccurate.

13.   **Suspension and Debarment**

Contractor certifies that it and its principals are not suspended or debarred from doing business with the state or federal government as listed on the *State of Texas Debarred Vendor List* maintained by the Texas Comptroller of Public Accounts and the *System for Award Management (SAM)* maintained by the General Services Administration. This certification is made pursuant to the regulations implementing Executive Order 12549 and Executive Order 12689, Debarment and Suspension, 2 C.F.R. Part 376, and any relevant regulations promulgated by the Department or Agency funding this project. This provision shall be included in its entirety in Contractor's subcontracts, if any, if payment in whole or in part is from federal funds.

14.   **Excluded Parties**

Contractor certifies that it is not listed in the prohibited vendors list authorized by Executive Order 13224, *"Blocking Property and Prohibiting Transactions with Persons Who Commit, Threaten to Commit, or Support Terrorism,"* published by the United States Department of the Treasury, Office of Foreign Assets Control.'

15.   **Foreign Terrorists Organizations**

Contractor represents and warrants that it is not engaged in business with Iran, Sudan, or a foreign terrorist organization, as prohibited by Section 2252.152 of the Texas Government Code.

16.   **Executive Head of a State Agency**

In accordance with Section 669.003 of the Texas Government Code, relating to contracting with the executive head of a state agency, Contractor certifies that it is not (1) the executive head of an HHS agency, (2) a person who at any time during the four years before the date of this Contract was the executive head of an HHS agency, or (3) a person who employs a current or former executive head of an HHS agency.

17. Human Trafficking Prohibition

Under Section 2155.0061 of the Texas Government Code, Contractor certifies that the individual or business entity named in this Contract is not ineligible to receive this contract and acknowledges that this Contract may be terminated and payment withheld if this certification is inaccurate.

18. Franchise Tax Status

Contractor represents and warrants that it is not currently delinquent in the payment of any franchise taxes owed the State of Texas under Chapter 171 of the Texas Tax Code.

19. Debts and Delinquencies

Contractor agrees that any payments due under this Contract shall be applied towards any debt or delinquency that is owed to the State of Texas.

20. Lobbying Prohibition

Contractor represents and warrants that payments to Contractor and Contractor's receipt of appropriated or other funds under this Contract or any related Solicitation are not prohibited by Sections 556.005, 556.0055, or 556.008 of the Texas Government Code (relating to use of appropriated money or state funds to employ or pay lobbyists, lobbying expenses, or influence legislation).

21. Buy Texas

Contractor agrees to comply with Section 2155.4441 of the Texas Government Code, requiring the purchase of products and materials produced in the State of Texas in performing service contracts.

22. Disaster Recovery Plan

Contractor agrees that upon request of System Agency, Contractor shall provide copies of its most recent business continuity and disaster recovery plans.

23. Technology Access

A. Contractor expressly acknowledges that state funds may not be expended in connection with the purchase of an automated information system unless that system meets certain statutory requirements relating to accessibility by persons with visual impairments. Accordingly, Contractor represents and warrants to System Agency that the technology provided to System Agency for purchase (if applicable under this Contract or any related Solicitation) is capable, either by virtue of features included within the technology or because it is readily adaptable by use with other technology, of:
   i. providing equivalent access for effective use by both visual and non-visual means;
   ii. presenting information, including prompts used for interactive communications, in formats intended for non-visual use; and
   iii. being integrated into networks for obtaining, retrieving, and disseminating information used by individuals who are not blind or visually impaired.
B. For purposes of this Section, the phrase "equivalent access" means a substantially similar ability to communicate with or make use of the technology, either directly by features incorporated within the technology or by other reasonable means such as

assistive devices or services which would constitute reasonable accommodations under the Americans With Disabilities Act or similar state or federal laws. Examples of methods by which equivalent access may be provided include, but are not limited to, keyboard alternatives to mouse commands and other means of navigating graphical displays, and customizable display appearance.

C. In accordance with Section 2157.005 of the Texas Government Code, the Technology Access Clause contract provision remains in effect for any contract entered into before September 1, 2006.

24. Computer Equipment Recycling Program

If this Contract is for the purchase or lease of computer equipment, then Contractor certifies that it is in compliance with Subchapter Y, Chapter 361 of the Texas Health and Safety Code related to the Computer Equipment Recycling Program and the Texas Commission on Environmental Quality rules in 30 TAC Chapter 328.

25. Television Equipment Recycling

If this Contract is for the purchase or lease of covered television equipment, then Contractor certifies that it is compliance with Subchapter Z, Chapter 361 of the Texas Health and Safety Code related to the Television Equipment Recycling Program.

26. Cybersecurity Training

A. Contractor represents and warrants that it will comply with the requirements of Section 2054.5192 of the Texas Government Code relating to cybersecurity training and required verification of completion of the training program.

B. Contractor represents and warrants that if Contractor or Subcontractors, officers, or employees of Contractor have access to any state computer system or database, the Contractor, Subcontractors, officers, and employees of Contractor shall complete cybersecurity training pursuant to and in accordance with Government Code, Section 2054.5192.

27. Restricted Employment for Certain State Personnel

Contractor acknowledges that, pursuant to Section 572.069 of the Texas Government Code, a former state officer or employee of a state agency who during the period of state service or employment participated on behalf of a state agency in a procurement or contract negotiation involving Contractor may not accept employment from Contractor before the second anniversary of the date the Contract is signed or the procurement is terminated or withdrawn.

28. Disclosure of Prior State Employment

If this Contract is for consulting services under Chapter 2254 of the Texas Government Code, in accordance with Section 2254.033 of the Texas Government Code, Contractor certifies that it does not employ an individual who was employed by System Agency or another agency at any time during the two years preceding the submission of any related

Solicitation Response related to this Contract or, in the alternative, Contractor has disclosed in any related Solicitation Response the following:

    i.   the nature of the previous employment with System Agency or the other agency;
    ii.   the date the employment was terminated; and
    iii.   the annual rate of compensation at the time of the employment was terminated.

29.   No Conflicts of Interest

A. Contractor represents and warrants that it has no actual or potential conflicts of interest in providing the requested goods or services to System Agency under this Contract or any related Solicitation and that Contractor's provision of the requested goods and/or services under this Contract and any related Solicitation will not constitute an actual or potential conflict of interest or reasonably create an appearance of impropriety.

B. Contractor agrees that, if after execution of the Contract, Contractor discovers or is made aware of a Conflict of Interest, Contractor will immediately and fully disclose such interest in writing to HHSC. In addition, Contractor will promptly and fully disclose any relationship that might be perceived or represented as a conflict after its discovery by Contractor or by HHSC as a potential conflict. HHSC reserves the right to make a final determination regarding the existence of Conflicts of Interest, and Contractor agrees to abide by HHSC's decision.

30.   Fraud, Waste, and Abuse

Contractor understands that System Agency does not tolerate any type of fraud. The agency's policy is to promote consistent, legal, and ethical organizational behavior by assigning responsibilities and providing guidelines to enforce controls. Violations of law, agency policies, or standards of ethical conduct will be investigated, and appropriate actions will be taken. All employees or contractors who suspect fraud, waste or abuse (including employee misconduct that would constitute fraud, waste, or abuse) are required to immediately report the questionable activity to both the Health and Human Services Commission's Office of the Inspector General at 1-800-436-6184 and the State Auditor's Office. Contractor agrees to comply with all applicable laws, rules, regulations, and System Agency policies regarding fraud including, but not limited to, HHS Circular C-027.

31.   Antitrust

The undersigned affirms under penalty of perjury of the laws of the State of Texas that:

A. in connection with this Contract and any related Solicitation Response, neither I nor any representative of the Contractor has violated any provision of the Texas Free Enterprise and Antitrust Act, Tex. Bus. & Comm. Code Chapter 15;

B. in connection with this Contract and any related Solicitation Response, neither I nor any representative of the Contractor has violated any federal antitrust law; and

C. neither I nor any representative of the Contractor has directly or indirectly communicated any of the contents of this Contract and any related Solicitation Response to a competitor of the Contractor or any other company, corporation, firm, partnership or individual engaged in the same line of business as the Contractor.

32.   Legal and Regulatory Actions

Contractor represents and warrants that it is not aware of and has received no notice of any court or governmental agency proceeding, investigation, or other action pending or threatened against Contractor or any of the individuals or entities included in numbered paragraph 1 of these Contract Affirmations within the five (5) calendar years immediately preceding execution of this Contract or the submission of any related Solicitation Response that would or could impair Contractor's performance under this Contract, relate to the contracted or similar goods or services, or otherwise be relevant to System Agency's consideration of entering into this Contract. If Contractor is unable to make the preceding representation and warranty, then Contractor instead represents and warrants that it has provided to System Agency a complete, detailed disclosure of any such court or governmental agency proceeding, investigation, or other action that would or could impair Contractor's performance under this Contract, relate to the contracted or similar goods or services, or otherwise be relevant to System Agency's consideration of entering into this Contract. In addition, Contractor acknowledges this is a continuing disclosure requirement. Contractor represents and warrants that Contractor shall notify System Agency in writing within five (5) business days of any changes to the representations or warranties in this clause and understands that failure to so timely update System Agency shall constitute breach of contract and may result in immediate contract termination.

33.   No Felony Criminal Convictions

Contractor represents that neither Contractor nor any of its employees, agents, or representatives, including any subcontractors and employees, agents, or representative of such subcontractors, have been convicted of a felony criminal offense or that if such a conviction has occurred Contractor has fully advised System Agency in writing of the facts and circumstances surrounding the convictions.

34.   Unfair Business Practices

Contractor represents and warrants that it has not been the subject of allegations of Deceptive Trade Practices violations under Chapter 17 of the Texas Business and Commerce Code, or allegations of any unfair business practice in any administrative hearing or court suit and that Contractor has not been found to be liable for such practices in such proceedings. Contractor certifies that it has no officers who have served as officers of other entities who have been the subject of allegations of Deceptive Trade Practices violations or allegations of any unfair business practices in an administrative hearing or court suit and that such officers have not been found to be liable for such practices in such proceedings.

35.   Entities that Boycott Israel

Pursuant to Section 2271.002 of the Texas Government Code, Contractor certifies that either:

    i.   it meets an exemption criteria under Section 2271.002; or
    ii. it does not boycott Israel and will not boycott Israel during the term of the contract resulting from this Solicitation. If Contractor refuses to make that certification,

Contractor shall state here any facts that make it exempt from the boycott certification:

_____

_____

_____ .

36. E-Verify Program

Contractor certifies that for contracts for services, Contractor shall utilize the U.S. Department of Homeland Security's E-Verify system during the term of this Contract to determine the eligibility of:

   i. all persons employed by Contractor to perform duties within Texas; and

   ii. all persons, including subcontractors, assigned by Contractor to perform work pursuant to this Contract within the United States of America.

37. Professional or Consulting Contract

If this Contract is an employment contract, a professional services contract under Chapter 2254 of the Texas Government Code, or a consulting services contract under Chapter 2254 of the Texas Government Code, Contractor represents and warrants that neither Contractor nor any of Contractor's employees including, but not limited to, those authorized to provide services under the contract, were former employees of an HHS Agency during the twelve (12) month period immediately prior to the date of the execution of the contract.

38. Former Agency Employees

Contractor represents and warrants, during the twelve (12) month period immediately prior to the date of the execution of this Contract, none of its employees including, but not limited to those who will provide services under the Contract, was an employee of an HHS Agency. Pursuant to Section 2252.901, Texas Government Code (relating to prohibitions regarding contracts with and involving former and retired state agency employees), Contractor will not allow any former employee of the System Agency to perform services under this Contract during the twelve (12) month period immediately following the employee's last date of employment at the System Agency.

39. Disclosure of Prior State Employment

If this Contract is for consulting services,

A. In accordance with Section 2254.033 of the Texas Government Code, a Contractor providing consulting services who has been employed by, or employs an individual who has been employed by, HHSC or another State of Texas agency at any time during the two years preceding the submission of Contractor's offer to provide services must disclose the following information in its offer to provide services. Contractor hereby certifies that this information was provided and remains true, correct, and complete:

   i. Name of individual(s) (Respondent or employee(s));

   ii. Status;

   iii. The nature of the previous employment with HHSC or the other State of Texas agency;

    iv.   The date the employment was terminated and the reason for the termination; and

    v.   The annual rate of compensation for the employment at the time of its termination.

B. If no information was provided in response to Section A above, Contractor certifies that neither Contractor nor any individual employed by Contractor was employed by HHSC or any other State of Texas agency at any time during the two years preceding the submission of Contractor's offer to provide services.

40.   Abortion Funding Limitation

Contractor understands, acknowledges, and agrees that, pursuant to Article IX, Section 6.25 of the General Appropriations Act (the Act), to the extent allowed by federal and state law, money appropriated by the Texas Legislature may not be distributed to any individual or entity that, during the period for which funds are appropriated under the Act:

    i.   performs an abortion procedure that is not reimbursable under the state's Medicaid program;

    ii.   is commonly owned, managed, or controlled by an entity that performs an abortion procedure that is not reimbursable under the state's Medicaid program; or

    iii.   is a franchise or affiliate of an entity that performs an abortion procedure that is not reimbursable under the state's Medicaid program. The provision does not apply to a hospital licensed under Chapter 241, Health and Safety Code, or an office exempt under Section 245.004(2), Health and Safety Code. Contractor represents and warrants that it is not ineligible, nor will it be ineligible during the term of this Contract, to receive appropriated funding pursuant to Article IX, Section 6.25.

41.   Funding Eligibility

Contractor understands, acknowledges, and agrees that, pursuant to Chapter 2272 of the Texas Government Code, except as exempted under that Chapter, HHSC cannot contract with an abortion provider or an affiliate of an abortion provider. Contractor certifies that it is not ineligible to contract with HHSC under the terms of Chapter 2272 of the Texas Government Code. If Contractor refuses to make that certification, Contractor shall state here any facts that make it exempt from the certification:

_____

_____

_____.

42.   False Representation

Contractor understands, acknowledges, and agrees that any false representation or any failure to comply with a representation, warranty, or certification made by Contractor is subject to all civil and criminal consequences provided at law or in equity including, but not limited to, immediate termination of this Contract.

43.   False Statements

Contractor represents and warrants that all statements and information prepared and submitted by Contractor in this Contract and any related Solicitation Response are current, complete, true, and accurate. Contractor acknowledges any false statement or material

misrepresentation made by Contractor during the performance of this Contract or any related Solicitation is a material breach of contract and may void this Contract. Further, Contractor understands, acknowledges, and agrees that any false representation or any failure to comply with a representation, warranty, or certification made by Contractor is subject to all civil and criminal consequences provided at law or in equity including, but not limited to, immediate termination of this Contract.

44.   Permits and License

Contractor represents and warrants that it will comply with all applicable laws and maintain all permits and licenses required by applicable city, county, state, and federal rules, regulations, statutes, codes, and other laws that pertain to this Contract.

45.   Drug-Free Workplace

Contractor represents and warrants that it shall comply with the applicable provisions of the Drug-Free Work Place Act of 1988 (41 U.S.C. §701 et seq.) and maintain a drug-free work environment.

46.   Equal Employment Opportunity

Contractor represents and warrants its compliance with all applicable duly enacted state and federal laws governing equal employment opportunities.

47.   Federal Occupational Safety and Health Law

Contractor represents and warrants that all articles and services shall meet or exceed the safety standards established and promulgated under the Federal Occupational Safety and Health Act of 1970, as amended (29 U.S.C. Chapter 15).

48.   Signature Authority

Contractor represents and warrants that the individual signing this Contract Affirmations document is authorized to sign on behalf of Contractor and to bind the Contractor.

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Attachment D

Authorized representative on behalf of Contractor must complete and sign the following:

PerkinElmer Health Sciences, Inc.
_____
Legal Name of Contractor

_____
Assumed Business Name of Contractor, if applicable (D.B.A. or 'doing business as')

_____
Texas County(s) for Assumed Business Name (D.B.A. or 'doing business as')
Attach Assumed Name Certificate(s) for each County

DocuSigned by:

Judy albrecht
AC1C1A7FD3684D2...   August 20, 2020
_____   _____
Signature of Authorized Representative   **Date Signed**

Judith A. Albrecht   8/20/20
_____   _____
Printed Name of Authorized Representative   **Title of Authorized Representative**
First, Middle Name or Initial, and Last Name

710 Bridgeport Avenue   Shelton, CT 06484
_____   _____
Physical Street Address   **City, State, Zip Code**

_____   _____
Mailing Address, if different   **City, State, Zip Code**

800-762-4000
_____   _____
Phone Number   **Fax Number**

Judith.Albrecht@perkinelmer.com   132010856
_____   _____
Email Address   **DUNS Number**

04-3361624   10433616249
_____   _____
Federal Employer Identification Number   **Texas Payee ID No. – 11 digits**

10433616249   11534306
_____   _____
Texas Franchise Tax Number   **Texas Secretary of State Filing**
                                                  Number

Health and Human Services (HHS)

Additional Provisions

Table of Contents

ADDITIONAL PROVISIONS

The terms and conditions of these Additional Provisions are incorporated into and made a part of the Contract. Capitalized items used in these Additional Provisions and not otherwise defined have the meanings assigned to them in HHSC Uniform Terms and Conditions.

1. **TURNOVER PLAN**

   HHSC, in its sole discretion, may require Contractor to develop and submit a Turnover Plan at any time during the term of the Contract. Contractor must submit the Turnover Plan to HHSC for review and approval. The Turnover Plan must describe Contractor's policies and procedures that will ensure:

   A. The least disruption in the delivery of the Work during Turnover to HHSC or its designee; and

   B. Full cooperation with HHSC or its designee in transferring the Work and the obligations of the Contract.

2. **TURNOVER ASSISTANCE**

   Contractor will provide any assistance and actions reasonably necessary to enable HHSC or its designee to effectively close out the Contract and transfer the Work and the obligations of the Contract to another vendor or to perform the Work by itself. Contractor agrees that this obligation survives the termination, regardless of whether for cause or convenience, or the expiration of the Contract and remains in effect until completed to the satisfaction of HHSC.

3. **NOTICE OF CRIMINAL ACTIVITY AND DISCIPLINARY ACTIONS**

   A. Contractor shall immediately report in writing to its assigned HHSC contract manager when Contractor learns of or has any reason to believe it or any person with ownership or controlling interest in Contractor, or their agent, employee, subcontractor or volunteer who is providing services under this Contract has:

      1. Engaged in any activity that could constitute a criminal offense equal to or greater than a Class A misdemeanor or grounds for disciplinary action by a state or federal regulatory authority; or

      2. Been placed on community supervision, received deferred adjudication, or been indicted for or convicted of a criminal offense relating to involvement in any financial matter, federal or state program or felony sex crime.

   B. Contractor shall not permit any person who engaged, or was alleged to have engaged, in any activity subject to reporting under this section to perform direct client services or have direct contact with clients, unless otherwise directed in writing by the System Agency.

4. **NOTICE OF IRS OR TWC INSOLVENCY**

   Contractor shall notify in writing its assigned HHSC contract manager of any insolvency, incapacity or outstanding unpaid obligations of Contractor owed to the Internal Revenue Service or the State of Texas, or any agency or political subdivision of the State of Texas within five days of the date of Contractor's becoming aware of such.

5. **NOTICE OF A LICENSE ACTION**

Contractor shall notify its assigned HHSC contract manager of any action impacting Contractor's license to provide services under this Contract within five days of becoming aware of the action and include the following:

A. Reason for such action;

B. Name and contact information of the local, state or federal department or agency or entity;

C. Date of the license action; and

D. License or case reference number.

6. **NOTICE OF CONTRACT ACTION**

Contractor shall notify their assigned contract manager if Contractor has had any contract suspended or terminated for cause by any local, state or federal department or agency or nonprofit entity within five days of becoming aware of the action and include the following:

A. Reason for such action;

B. Name and contact information of the local, state or federal department or agency or entity;

C. Date of the contract;

D. Date of suspension or termination; and

E. Contract or case reference number.

7. **NOTICE OF BANKRUPTCY**

Contractor shall notify in writing its assigned contract manager of its plan to seek bankruptcy protection within five days of such action by Contractor.

8. **CONTRACTOR'S NOTIFICATION OF CHANGE OF CONTACT PERSON OR KEY PERSONNEL**

The Contractor shall notify in writing their contract manager assigned within ten days of any change to the Contractor's Contact Person or Key Personnel.

9. **INTERIM EXTENSION AMENDMENT**

A. Prior to or on the expiration date of this Contract, the Parties agree that this Contract can be extended as provided under this Section.

B. The System Agency shall provide written notice of interim extension amendment to the Contractor under one of the following circumstances:
   1. Continue provision of services in response to a disaster declared by the governor; and
   2. To ensure that services are provided to clients without interruption.

C. The System Agency will provide written notice of the interim extension amendment that specifies the reason for it and period of time for the extension.

D. Contractor will provide and invoice for services in the same manner that is stated in the Contract.

E. An interim extension under Section (b)(1) above shall extend the term of the contract not

longer than 30 days after governor's disaster declaration is declared unless the Parties agree to a shorter period of time.

F. An interim extension under Section (b)(2) above shall be a one-time extension for a period of time determined by the System Agency.

10. Electronic and Information Resources Accessibility and Security Standards

A. Applicability:

The following Electronic and Information Resources (EIR) requirements apply to the Contract because the Contractor performs services that include EIR that the System Agency's employees are required or permitted to access or members of the public are required or permitted to access.

This Section does not apply to incidental uses of EIR in the performance of the Agreement, unless the Parties agree that the EIR will become property of the State of Texas or will be used by HHSC's clients or recipients after completion of the Agreement. Nothing in this section is intended to prescribe the use of particular designs or technologies or to prevent the use of alternative technologies, provided they result in substantially equivalent or greater access to and use of a Product.

B. Definitions:

"Accessibility Standards" means accessibility standards and specifications for Texas agency and institution of higher education websites and EIR set forth in 1 TAC Chapter 206 and/or Chapter 213.

"**Electronic and Information Resources**" means information resources, including information resources technologies, and any equipment or interconnected system of equipment that is used in the creation, conversion, duplication, or delivery of data or information. The term includes telephones and other telecommunications products, information kiosks, transaction machines, Internet websites, multimedia resources, and office equipment, including copy machines and fax machines.

"Electronic and Information Resources Accessibility Standards" means the accessibility standards for electronic and information resources contained in 1 Texas Administrative Code Chapter 213.

"Product" means information resources technology that is, or is related to EIR.

"Web Site Accessibility Standards/ Specifications" means standards contained in Volume 1 Tex. Admin. Code Chapter 206(c) Accessibility Requirements.

C. Under Tex. Gov't Code Chapter 2054, Subchapter M, and implementing rules of the Texas Department of Information Resources, the System Agency must procure Products and services that comply with the Accessibility Standards when those Products are available in the commercial marketplace or when those Products are developed in response to a procurement solicitation. Accordingly, Contractor must provide electronic and information resources and associated Product documentation and technical support that comply with the Accessibility Standards.

D. Evaluation, Testing, and Monitoring

1. The System Agency may review, test, evaluate and monitor Contractor's Products and services, as well as associated documentation and technical support for compliance with the Accessibility Standards. Review, testing, evaluation and monitoring may be conducted before and after the award of a contract. Testing and monitoring may include user acceptance testing. Neither the review, testing (including acceptance testing), evaluation or monitoring of any Product or service, nor the absence of review, testing, evaluation or monitoring, will result in a waiver of the State's right to contest the Contractor's assertion of compliance with the Accessibility Standards.

2. Contractor agrees to cooperate fully and provide the System Agency and its representatives timely access to Products, records, and other items and information needed to conduct such review, evaluation, testing, and monitoring.

E. Representations and Warranties

1. Contractor represents and warrants that if the Products will be in the custody of the state or a System Agency's client or recipient after the Contract expiration or termination, the Products will continue to comply with Accessibility Standards after the expiration or termination of the Contract Term, unless the System Agency or its clients or recipients, as applicable, use the Products in a manner that renders it noncompliant.

2. Should this **Attachment E** become applicable to the Product (Specimen Gate software) documentation, Contractor will make a good faith effort to ensure that the documentation is consistent and compliant with Section 508 Standards, as practical and commercially reasonable, and use Section 508 Standards for guidance for designing accessible web pages for accessibility to people with disabilities at https://www.access-board.gov/guidelines-and-standards/communications-and-it/about-the-section-508-standards/section-508-standards.

3. Contractor acknowledges and agrees that these representations and warranties are essential inducements on which the System Agency relies in awarding this Contract. Contractor's representations and warranties under this subsection will survive the termination or expiration of the Contract and will remain in full force and effect throughout the useful life of the Product.

4. Contractor acknowledges and agrees that these representations and warranties are essential inducements on which the System Agency relies in awarding this Contract.

5. Contractor's representations and warranties under this subsection will survive the termination or expiration of the Contract and will remain in full force and effect throughout the useful life of the Product.

F. Remedies

1. Under Tex. Gov't Code § 2054.465, neither the Contractor nor any other person has cause of action against the System Agency for a claim of a failure to comply with Tex. Gov't Code Chapter 2054, Subchapter M, and rules of the Department of Information Resources.

2. In the event of a breach of Contractor's representations and warranties, Contractor will

be liable for direct, consequential, indirect, special, or liquidated damages and any other remedies to which the System Agency may be entitled under this Contract and other applicable law. This remedy is cumulative of any other remedies to which the System Agency may be entitled under this Contract and other applicable law.

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