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1. Service Overview

The Contractor agrees to provide the CDPH and/or GDSP the services described herein.

The Contractor shall perform high screening of newborn infants for primary congenital hypothyroidism, galactosemia, hemoglobinopathies, congenital adrenal hyperplasia, biotinidase deficiency, cystic fibrosis, various amino acid, organic acid, and acylcarnitine disorders in Newborn Screening (NBS). In addition, the contractor shall perform screening of newborn infants for Severe Combined Immunodeficiency (SCID) disorders when the reagent system becomes available. The contractor shall perform high volume screening of pregnant women in the 1st and 2nd Trimester to detect levels of alpha-fetoprotein, human chorionic gonadotropin (hCG), unconjugated estriol, and Inhibin-A, and pregnancy-associated plasma protein A (PAPP-A) in Prenatal Screening (PNS).

2. Service Location

The services shall be performed in applicable facilities within the awarded Region as show in the following subsection 5.D.

3. Service Hours

The services shall be provided, Monday through Sunday, 8:00 a.m. to 8:00 p.m., including holiday coverage, with an on-site supervisor.

4. Project Representatives

A. The project representatives during the term of this agreement will be:

California Department of Public Health	Contractor
Thomson Ho, PhD Acting Laboratory Director Telephone: (510) 231-1747 Fax: (510) 231-1738 Email: thomson.ho@cdph.ca.gov	Name: TBD Phone: TBD Fax: TBD Email: TBD

B. Direct all inquiries to:

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California Department of Public Health	Contractor
Thomson Ho, Ph.D., Acting Laboratory Chief Genetic Disease Screening Program 850 Marina Bay Parkway, G-265 Mail Stop 8201 Richmond, CA 94804	Attention: TBD
Telephone: (510) 231-1747	Address: TBD
Fax: (510) 231-1738	Telephone: TBD
Email: thomson.ho@cdph.ca.gov	Fax: TBD
	Email: TBD

- C. Either party may make changes to the information above by giving written notice to the other party. Said changes shall not require an amendment to this agreement.

5. Services to be Performed

Contractor shall perform the following services:

A. Newborn Screening (NBS) Panel:

The Contractor shall use the following CDPH designated screening tests and test methods for the laboratory detection of amino acids, acylcarnitines (Fatty Acids), galactosemia, primary congenital hypothyroidism, hemoglobinopathies, congenital adrenal hyperplasia, biotinidase deficiency, cystic fibrosis, and severe combined immunodeficiency (SCID).

i. Amino Acids:

Test for amino acids: Mass spectrometric analysis of eluates from blood spots using Micromass Quattro tandem mass spectrometer or subsequent upgrade provided by PerkinElmer or a subsequent replacement platform.

ii. Acylcarnitines_(Fatty Acids):

Test for acylcarnitines: Mass spectrometric analysis of eluates from blood spot using Micromass Quattro tandem mass spectrometer or subsequent upgrade provided by PerkinElmer or a subsequent replacement platform.

iii. Galactosemia:

Test for transferase (galactose-1-phosphate uridyl transferase): fluorometric analysis of eluates from blood spot by automated continuous flow using API 300 (or subsequent upgrade) provided by CDPH through

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Astoria-Pacific International specifically adapted for this purpose or other subsequent replacement platforms.

Primary Congenital Hypothyroidism:

Test for thyroid stimulating hormone (TSH): automated immunoassay using AutoDELFI A provided by CDPH through PerkinElmer or subsequent upgrade or a subsequent replacement platform.

iv. Hemoglobinopathies:

Test for Hemoglobin (Hb) Patterns: high performance liquid chromatography (HPLC) analysis of the eluate from blood spot for hemoglobin variants using automated equipment system provided by CDPH through Bio-Rad Laboratories.

v. Congenital Adrenal Hyperplasia:

Test for 17-hydroxyprogesterone (17OHP): automated immunoassay using AutoDELFI A provided by CDPH through PerkinElmer or subsequent upgrade or a subsequent replacement platform.

vi. Biotinidase Deficiency:

Test for biotinidase: colorimetric analysis of eluate from blood spot by automated continuous flow using API 300 from Astoria-Pacific International specifically adapted for this purpose or other subsequent replacement platforms or subsequent upgrade or a subsequent replacement platform.

vii. Cystic Fibrosis:

Test for immunoreactive trypsinogen (IRT): automated immunoassay using AutoDELFI A provided by CDPH through PerkinElmer or subsequent upgrade or a subsequent replacement platform.

viii. Severe Combined Immunodeficiency (SCID):

Test for Severe Combined Immunodeficiency markers (TREC and beta-actin) using reagent/instrument systems provided by CDPH through designated vendor or subsequent upgrade or a subsequent replacement platform.

B. Prenatal Screening (PNS) Panel - Second Trimester:

The Contractor shall use the CDPH designated screening tests and test methods for the laboratory detection of Alpha-fetoprotein (AFP), human Chorionic Gonadotropin (hCG), and unconjugated Estriol (uE3) in human

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serum, using the AutoDELFI A manufactured by PerkinElmer or subsequent upgrade or a subsequent replacement platform.

The Contractor shall use the CDPH designated screening tests and test methods for the laboratory detection of Inhibin-A in human serum, using the DSX Automated Immunoassay System manufactured by Beckman-Coulter, Inc. or a subsequent replacement platform.

C. Prenatal Screening (PNS) Panel - First Trimester:

The Contractor shall use the CDPH designated screening tests and test methods for the laboratory detection of PAPP-A and hCG in human serum, using the AutoDELFI A manufactured by PerkinElmer or a subsequent replacement platform.

D. Contractor shall provide 1st and 2nd trimester screening laboratory services for pregnant women who are patients of providers in their awarded Region. Contractor shall provide newborn screening laboratory services for infants who are born in their awarded Region. Geographic Area Regions #1-3 consist of the following counties:

Region 1

County				
Alameda	Humboldt	Monterey	San Luis Obispo	Stanislaus
Amador	Lake	Napa	San Mateo	Sutter
Butte	Lassen	Nevada	Santa Clara	Tehama
Calaveras	Madera	Placer	Santa Cruz	Trinity
Colusa	Marin	Plumas	Shasta	Tuolumne
Contra Costa	Mariposa	Sacramento	Sierra	Yolo
Del Norte	Mendocino	San Benito	Siskiyou	Yuba
El Dorado	Merced	San Francisco	Solano	
Glenn	Modoc	San Joaquin	Sonoma	

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Region 2	Region 3
County	County
Alpine	Los Angeles
Fresno	Santa Barbara
Imperial	Ventura
Inyo	
Kern	
Kings	
Mono	
Orange	
Riverside	
San Bernardino	
San Diego	
Tulare	

- E. Contractor shall perform such laboratory services according to the contract at the location named on the Contractor's current State of California Clinical Laboratory License and shall not subcontract any portion of this work.
- F. Contractor shall accept for testing newborn blood spot specimens, collected on special filter paper on State forms, from the hospitals and physicians in the contract area. Contractor shall accept for testing from the contract area blood specimens collected from pregnant women in serum separator tubes from clinicians and laboratory draw stations, in the contract area. Specimens will be sent to Contractor, through CDPH's designated account with Golden State Overnight, or other State designated courier service(s), at CDPH's expense. Specimens may also be sent via US Postal Service to a PO Box maintained by CDPH. Postage for mailed specimens will be paid by CDPH. Contractor will be responsible for pick-up of specimens from the PO Box and transport to the testing laboratory 6 days per week.

If through the error of the NAPS laboratory, a specimen is lost or cannot be tested, Contractor shall reimburse the blood drawing facility collecting the repeat specimen for costs of blood collection if requested.

- G. Contractor shall provide seven-day-per-week laboratory operation including holidays with an on-site supervisor; initiate newborn testing as soon as

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- possible (after specimen receipt) but in no case longer than 22 hours after receipt. Initiate 1st and 2nd trimester testing on prenatal specimens as soon as possible but in no case longer than 22 hours after receipt.
- H.** Contractor agrees that the major equipment, reagents, and consumables will be provided by CDPH to the Contractor for newborn and 1st and 2nd trimester screening tests as referenced in Section XV, Program Appendices, Appendix 7 List of Major Equipment, Reagents, and Consumables to be provided by CDPH. The major items of laboratory equipment referenced in Section XV, Program Appendices, Appendix 7, List of Major Equipment, Reagents, and Consumables to be supplied by CDPH, for the duration of the contract period, are to be used for purposes of this specified contract work only, unless otherwise authorized in writing by CDPH GDSP, and shall be returned to CDPH upon completion of the contract.
 - I.** Contractor shall provide all equipment items, reagents, and consumables necessary for the screening tests that are not provided by CDPH. Contractor agrees that Section XV, Program Appendices, Appendix 8, List of Major Equipment, Reagents, and Consumables to be provided by Contractor is a representative list of such equipment items, reagents, and consumables.
 - J.** Contractor agrees that whenever specific manufacturers or vendors of chemicals or reagents that are to be provided by Contractor, are named by CDPH, Contractor shall not use an equivalent chemical or reagent unless accuracy, precision or specificity are not affected adversely. Contractor shall provide data documenting equivalency of chemical or reagent.
 - K.** Contractor shall follow CDPH GDSP written method descriptions for NBS and PNS screening services, specimen accession, and data processing as provided for in Section XV, Program Appendices, Appendix 9, Data Entry and Follow-up Actions for Newborn and Prenatal Screening. CDPH reserves the right to make changes in the written methods or equipment to improve reliability or efficiency without re-negotiation of cost, provided there is no increase in Contractor's overall cost.
 - L.** Contractor agrees that CDPH reserves the right to add and/or delete test(s) during the course of the contract term. In the event that such changes result in an increase/decrease in Contractor's overall cost, CDPH and the Contractor shall mutually agree on an appropriate reimbursement rate(s); such agreement shall be in the form of a written amendment to the contract. All increases in cost shall be justified to the satisfaction of CDPH.
 - M.** Contractor agrees that any changes made by CDPH in the number of hospitals or physicians assigned to the service area will not significantly increase or decrease the volume of tests performed.

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- N.** Contractor shall use the CDPH-provided process controllers and barcode-printer-numbered-accession labels which are used for NBS and PNS specimens as described in Section XV, Program Appendices, Appendix 7 and Appendix 5a and 5k. CDPH shall provide to the Contractor the blank self-adhesive labels. In the event of non-functioning or unavailability of the process controllers or barcode printer, Contractor shall telephone and email CDPH GDSP to obtain accession numbers or printed accession labels.
- O.** Contractor shall act in accordance with and perform those actions designated in Section XV, Program Appendices, Appendix 9, Data Entry and Follow-up Actions for Newborn and Prenatal Screening. Contractor shall record and retain information from Contractor's telephoned report of an inadequate newborn specimen or report of a newborn presumptive positive result on the "Confirmation of Contact," panel in the SIS system which is described in Section XV, Program Appendices, Appendix 11, and referenced in Section XV, Program Appendices, Appendix 10. Contractor shall provide to GDSP daily key entry of data from the NBS-CC Form. Contractor shall record and retain information from Contractor's telephoned report of an inadequate NBS blood spot or 1st or 2nd trimester serum specimen as described in Section XV, Program Appendices, Appendix 10, and as referenced in Section XV, Program Appendices, Appendix 9.
- P.** Contractor shall notify GDSP by telephone and email when any test is inoperable and remains inoperable by 9:00 AM of the following day, or whenever any test is out of quality control limits and remains out of limits the next day. Transport of specimens shall be at GDSP expense. Contractor must follow GDSP instruction to transport specimens to another laboratory and take any action as directed to ensure prompt access to testing.
- Q.** Contractor shall provide to GDSP daily key entry of clinical demographic information from the specimen collection forms, the action related to inadequate specimens and the reporting of initial positives. Contractor shall obtain and provide this information to GDSP according to GDSP protocols.
- R.** Contractor shall electronically transmit analytical data from all runs daily, to include items such as calibration curves, quality control data and conclusions, and normal and abnormal test results.
- S.** Contractor shall follow procedures for laboratory and office equipment maintenance, equipment service, troubleshooting, record keeping, reporting, retention of specimens, and mailing of materials, as instructed by GDSP.
- T.** Contractor agrees that for GDSP-supplied equipment listed in Section XV, Program Appendices, Appendix 7, CDPH will provide maintenance and repair services under separate contract with equipment manufacturers. Contractor shall be responsible for purchasing toner cartridges for GDSP-supplied

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printers and invoice GDSP as necessary utilizing the budget identified under the Equipment Line of the Cost Proposal Summary Table. Contractor shall provide access at all times to maintenance and service personnel and to GDSP personnel. Contractor shall not service or repair and shall not allow a third party to service or repair any GDSP-supplied equipment or instruments.

- U.** Contractor shall fully and clearly communicate the nature of any instrument malfunction via telephone and email (or fax, if requested) to specified service personnel and/or GDSP personnel within 1 business day.
- V.** Contractor shall not operate the equipment negligently and shall not have untrained personnel operating the equipment.

Trained operators for the purpose of Newborn Screening are described below:

- 1) Persons who have received training from GDSP and/or Astoria-Pacific International for API, PerkinElmer for AutoDELFIA, Waters for MS/MS, and Bio-Rad for HPLC;
- 2) Persons who have operated these instruments routinely for three months under supervision.

Trained operators for the purpose of Prenatal Screening are described below:

1. Persons who have received training from GDSP and/or PerkinElmer, Inc. and Beckman-Coulter or their designated agents or,
2. Persons who have operated an AutoDELFIA instrument and DSX routinely for three months under supervision.

- W.** Contractor shall maintain an up-to-date Log of Service for GDSP supplied equipment. This Log shall be maintained in accordance with guidelines provided by GDSP.
- X.** Contractor shall participate in the GDSP proficiency-testing program and GDSP specified professional proficiency testing programs, and be subject to continuous and constant contact and consultation by GDSP including on-site review of any NAPS laboratory function.
- Y.** Contractor shall provide newborn and prenatal screening overload testing capability of 50% for a period of at least 30 days.
 - i. Such overload testing capability shall be available for CDPH's use, to the extent it is needed as determined by CDPH and/or whenever services are interrupted in any one or more of the other screening laboratories. In such cases, Contractor shall accept and test newborn and/or prenatal

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specimens from areas other than their awarded Newborn and Prenatal Screening Region, as designated by CDPH. Contractor shall provide for the overload specimens testing, reporting and actions specified in this contract for their awarded Region, except that Contractor shall communicate with the Newborn Screening Coordinator(s) and the Prenatal Screening Coordinator(s) designated by CDPH for the overload specimens.

- ii. CDPH shall be responsible for expenses related to delivery of overload specimens to Contractor; Contractor shall make no additional charges to CDPH for communications associated with overload specimens.
- iii. Upon written request by CDPH, Contractor shall arrange for and continue overload testing in addition to the initial 30 day period for successive 30 day periods, in order that statewide screening continue without interruption.
- iv. In the event that such overload testing continues for a period of 90 days, successively, Contractor agrees that CDPH may require that the overload testing become permanent for the remainder of the contract period.
- v. In addition to the payments for NBS specimens in their awarded Region, any specimens redirected from other Regions will be paid to the Contractor at the awarded reimbursement rates.
- vi. In addition to the payments for PNS specimens for their awarded Region, any specimens redirected from other Regions will be paid to the Contractor at the awarded reimbursement rates.
- vii. Contractor shall be subject to frequent proficiency-testing for all assays as determined by CDPH and required to enroll in professional proficiency testing programs specified by GDSP. Contractor shall be subject to testing of overload capacity, and on-site inspections. Contractor shall be subject to continuous and constant contact, review and consultation by GDSP staff, including review of data and records, compliance with items in Contractor's technical proposal, and the operation of any other NBS and PNS screening NAPS Laboratory functions.
- viii. Contractor shall have an effective working relationship with hospitals, physicians and area genetic centers/case coordination centers to assure fast and accurate newborn and 1st and 2nd trimester screening in the contract area. Contractor shall not send or otherwise distribute any communication to the above mentioned institutions or individual without prior written approval from GDSP to assure that such communication is consistent with State policies and regulations. The contractor shall

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maintain patient(s) confidentiality as required by State and Federal regulations.

- ix. If CDPH determines that the Contractor does not meet standards of acceptable laboratory or medical practice, CDPH shall require the Contractor to immediately suspend all testing of newborn and prenatal screening covered by the contract for the period deemed necessary by CDPH. In such cases, the Contractor shall, on notification by CDPH in writing, route all specimens to another NAPS laboratory designated by CDPH and shall not resume testing until notified by CDPH in writing. Contractor shall relinquish GDSP supplied laboratory equipment, within a period designated by the GDSP on written notice.
- x. Return of specimens to GDSP: upon completion of testing, all dried blood spots shall be directly or in certain cases, indirectly, returned to GDSP. Specimens that are screened positive for IRT shall be sent to the State's cystic fibrosis mutation panel analysis laboratory. Shipping for these purposes will be at the expense of CDPH using CDPH designated method of transportation.

Prenatal screening specimens shall be stored for up to 30 days on site and then destroyed unless they are from a county whose specimens are designated to be stored in the CDPH Biobank or CDPH has requested they be sent to GDSP for storage. Specimens sent to the CDPH Biobank or to GDSP will be shipped at CDPH's expense using CDPH designated method of transportation. Routinely, all 2nd trimester specimens from the following counties will be sent to the California Biobank Program for storage: Fresno, Kern, Kings, Tulare, Merced, Orange, and San Diego.

- xi. Staff designated by GDSP shall attend training as required for new testing methods and data entry changes.
- xii. CDPH may direct the Contractor staff to attend training. Any and all travel must be preapproved by CDPH. In such situations, CDPH shall reimburse the Contractor for the actual costs for CDPH-approved and required Contractor Staff travel mileage, lodging, and per diem costs up to the maximum allowed in accordance with the guidelines currently in effect, as established by the California Department of Personnel Administration (DPA), for non-represented State employees. If the DPA rates change during the term of the agreement, the new rates shall apply upon their effective date and no amendment to this agreement shall be necessary. Exceptions to DPA rates may be approved by CDPH upon the submission of a statement by the contractor indicating that such rates are not available to the Contractor Staff. No travel outside the State of California shall be reimbursed without prior written authorization from GDSP. CDPH

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shall provide the Contractor with a Travel Reimbursement form to be completed and attached, with all applicable receipts, to the Contractor's invoice for payment.

6. Staffing Changes

CDPH recognizes that resignation or other events may cause the Laboratory Director and Supervisory Personnel Contractor Staff members to no longer be available to the Contractor. If this occurs, Contractor shall notify the GDSP in writing of the resignation within five (5) business days of the resignation or other event causing these Contractor Staff members unavailability.

GDSP reserves the right to approve replacement of the Laboratory Director and Supervisory Personnel supplied by the Contractor.

The Contractor shall present to GDSP at least one resume for any new or replacement staff for the Laboratory Director and Supervisory Personnel for potential approval or disapproval at least fifteen (15) business days before the new candidate is to start working on the Contract. The proposed replacement must clearly meet, or exceed, the same qualification requirements met at time of contract award for the areas listed in Section V, Respondent's Response Requirements, Subsection E, Contractor Personnel. Further, the replacement must possess the same certifications and/or licenses as required by CDPH and originally possessed by the named Contract Staff member. This information must be clearly shown in the proposed candidates' resume.

GDSP reserves the right to disapprove the continuing assignment of the Laboratory Director and Supervisory Personnel supplied by the Contractor under this Contract.