

800 East Capitol Avenue | Pierre, SD 57501 Phone: 773 330-7600, 773 6085



Division of Health and Medical Services
Community Health Services
Disease Prevention
Family Health
Health Promotion
State Epidemiologist

July 5, 2012

Angi Roemerman
Professional Departmental Assistant
University of Iowa
Division of Sponsored Programs
2 Gilmore Hall
Iowa City, IA 52242

Dear Angi:

Enclosed is your original signed copy of the contract between the South Dakota Department of Health and the State Hygienic Laboratory at the University of Iowa for June 1, 2012 through May 31, 2015.

Thank you for your assistance in the process. If you have any questions, please contact me at 605-773-2944.

Sincerely,

A large black rectangular redaction box covering the signature of Lucy Fossen.

Lucy Fossen, RN
South Dakota Newborn Screening Program

Cc: Stanton Berberich

Enclosures: 1

STATE OF SOUTH DAKOTA
CONSULTANT CONTRACT/LETTER OF AGREEMENT
FOR CONSULTANT SERVICES
BETWEEN

The University of Iowa
On behalf of the State Hygienic Laboratory
2 Gilmore Hall
Iowa City, Iowa 52242
Referred to as "Consultant"

South Dakota Department of Health
Division of Health and Medical Services
Office of Family and Community Health
615 East 4th Street
Pierre, SD 57501
Referred to as "State"

State and Consultant hereby enter into a contract for Consultant Services.

I. CONSULTANT

- A. The term of this Contract shall begin June 1, 2012 and end May 31, 2015 with the option to renew for two (2) additional one (1) year extensions at the State's discretion and by mutual agreement. State will not pay for any services provided by Consultant unless this contract is signed by all parties BEFORE CONSULTANT BEGINS TO PROVIDE SERVICES.
- B. Consultant is not a full or part-time employee of State or any agency of the state of South Dakota.
- C. Consultant, as an independent contractor, is solely responsible for the withholding and payment of applicable income and Social Security taxes due and owing from money received under this contract.
- D. Consultant will not use equipment, supplies or facilities owned by the state of South Dakota.
- E. Consultant will not purchase capital assets or equipment using State funds.
- F. Consultant agrees to:
 - 1. Provide newborn screening testing with analysis in a CLIA certified laboratory (Clinical Laboratory Improvement Amendments of 1988) at a fixed site.
 - 2. Provide accurate and timely newborn screening testing and analysis of initial and repeat dried blood spot specimens for the following disorders: biotinidase deficiency, cystic fibrosis; congenital hypothyroidism; congenital adrenal hyperplasia; galactosemia; hemoglobinopathies; and

disorders detected by tandem mass spectrometry including fatty acid oxidation disorders; amino acid disorders and organic acid disorders.

3. Participate in the Newborn Screening Quality Assurance Program (NSQAP) if available, for each laboratory method used to analyze specimens. For tests of disorders not covered by the NSQAP, the consultant must implement a self-administered performance evaluation system and maintain appropriate records, or, if available, participate in performance testing services for this disorder.
4. Upon State's request provide flow charts for each analysis scheme for each disorder with cutoff decisions for specimens yielding positive test results and the responsible personnel identified.
5. Upon State's request, provide quality assurance data (e.g. personnel qualifications and competency, standard operating procedures, specimen collection).
6. Report to State all testing delays (e.g., due to equipment breakdown, reagent problems) of greater than 24 hours beyond the laboratory's standard operating procedures once recognized and plans to alleviate the delay (e.g., new replacement parts or reagent ordered).
7. Provide newborn screening collection devices as recommended by the current edition of "Blood Collection on Filter Paper for Newborn Screening Programs", Clinical and Laboratory Standards Institute.
 - a. Ensure collection devices include printed instructions on form completion, storage of collection paper, blood specimen collection, and courier pickup or mailing instructions.
 - b. Ensure the following demographic and other identifying information are printed on the test requisition for completion by the submitter:
 - First and last name of newborn;
 - Date and time of birth of newborn;
 - Sex of newborn;
 - Unique identification number of newborn for matching with the birth certificate;
 - First, last and maiden name of mother;
 - Address, including street, city, state, and zip code of mother;

- Submitting facility;
 - Facility of birth;
 - Physician name;
 - Date and time of specimen collection;
 - Initial or repeat specimen;
 - Feeding method
 - Weight of infant in grams; and
 - Status of newborn – premature or transfused with date of most recent transfusion.
- c. Ensure information collected on the test requisition, including any proposed changes, is approved by State prior to use and complies with the needs of State.
 - d. Ensure lines of communication are established with the appropriate personnel of each hospital and healthcare collection facility to ensure the smooth operation of the collection of specimens.
 - e. Distribute adequate collection supplies to each hospital and healthcare collection facility in South Dakota.
 - f. Retain dried blood spots for 30 days after completion of testing and then have them destroyed. Storage of the residual dried blood spots will be maintained at Consultant's facility in a manner that provides security, confidentiality, stability of temperature and humidity, and retrievability. Once a month specimens will be securely transported and destroyed by the medical waste disposal company contracted by Consultant. Verification of the handling and destruction of the dried blood spots will be documented and maintained. Provide to the State monthly verification the residual dried blood spots are accounted for and their destruction is complete.
8. Consultant agrees to ensure procedures are in place to transport specimens within 24 hours for next day delivery during normal business days, as soon thereafter as possible on weekends and holidays given the current delivery service's work schedule.
 9. Consultant will provide means of providing newborn screening laboratory reports to all submitters of newborn screening specimens.
 10. Provide immediate notification to the submitting facility and State regarding:

- a. Unsatisfactory and/or specimens of poor quality and the need for a repeat specimen. Notification to the submitting facility should include reason specimen was unsatisfactory and the appropriate time frame for obtaining the repeat specimen. This shall be no later than 24 hours after the analysis or within four working days of specimen receipt, whichever is earlier.
 - b. Newborn screening specimens collected less than 24 hours of age and the need for a repeat specimen.
11. Provide notification of abnormal newborn screening test results:
- a. Within one working day of laboratory analysis to the named physician on the test requisition by telephone and facsimile, and/or electronic mail. On weekends and holidays only positive test results for Congenital Adrenal Hyperplasia (CAH); Galactosemia (GALT) and Tandem Mass Spectrometry Disorders (TMS) will be reported within 24 hours.
 - b. Lab results for Biotinidase Deficiency (BD), Cystic Fibrosis (CF); Hemoglobinopathy (Hgb); Congenital Hypothyroidism (CH) and borderline results will be reported to primary care physicians on regular workdays, not weekends or holidays.
 - c. For every positive test result notification to the provider, recommendations of further testing and treatment is to be included. Documentation of the date(s) of telephone and facsimile notification, the name of the responsible physician/healthcare provider notified, the collection facility, the name of the person contacted, a copy of facsimile communication, and the name of the person making the contact shall be provided to State.
12. Consultant will provide upon request, a summary of disaster response plan(s) to provide laboratory testing of the newborn screening specimens in the event of emergency, natural disaster or other event causing a delay of more than five (5) days or more in testing, and requiring specimens to be tested at another location until such time as the designated laboratory is able to resume testing. If the response plan includes written agreements with other laboratories, it shall specify responsibilities of each laboratory involved, specimen transportation, testing and notification of submitter, physician and State of results. Should a laboratory disaster destroy patient samples, the laboratory and State will make every effort to contact the appropriate client requesting resubmission of samples. Consultant will

obtain prior approval from the State when using South Dakota specimens for Emergency Preparedness Drills.

13. Provide education training regarding newborn screening specimen collection and laboratory testing to healthcare providers and State staff upon request of State.
14. Electronically transmit test results and other data via a secure connection. All electronic transmissions of data must meet all state and Federal security requirements including those of the Bureau of Information and Telecommunications (BIT) and Health Insurance Portability and Accountability Act (HIPAA). Data elements will be submitted in a fixed ASCII file and include at a minimum.
 - First and last name of newborn;
 - Date and time of birth of newborn;
 - Sex of newborn;
 - Unique identification number of newborn for matching with the birth certificate;
 - First, last and maiden name of mother;
 - Address, including street, city, state, and zip code, of mother;
 - Hospital of birth;
 - Physician name;
 - Submitting facility;
 - Laboratory number;
 - Date and time of specimen collection;
 - Feeding method;
 - Weight of infant;
 - Gestation age/prematurity
 - Status of transfusion with date of most recent transfusion; and
 - Test results
15. Provide 5x a week, electronic transmission of newborn screening test results via fixed ASCII file and newborn screening laboratory reports in PDF format.
16. Notify the State of all corrected and/or revised laboratory reports.
17. Upon State's request, provide newborn screening laboratory data for

national reporting purposes and survey requests to State (e.g. National Newborn Screening and Genetics Resource Center, Heartland Collaborative, CDC data requests).

18. Notify State if routine newborn screening laboratory testing is to be performed by someone other than the Consultant. That laboratory may be used only with the express prior written consent of State.
19. Ensure all policies and procedures, including any proposed changes relevant to newborn screening, are approved by State prior to implementation and complies with needs of State.
20. A copy of all relevant policies and procedures must be submitted to State within 30 days of effective date of contract.
21. Provide for any future needs of State. Negotiate with State any future newborn screening laboratory service needs and amend contract to include mutually agreeable additional services.
22. Direct bill each submitting health care provider or birthing facility monthly, according to the fee schedule in (fee schedule attachment), attaché hereto and incorporated herein.

G. **INSURANCE:** Consultant satisfies all claims against it in its capacity as a self-insured agency of State of Iowa government. The consultant is covered as follows:

1. Commercial General Liability Insurance:

Liability claims against the State of Iowa as provided by Chapters 25 and 669 of the Iowa Code (2011).

2. Business Automobile Liability Insurance:

Self-insurance pool for purposes of vehicular liability, including owned, non-owned and rental vehicles.

Vehicular liability claims exceeding \$250,000 are processed in accordance with the Iowa Tort Claims Act, set forth in Chapter 669, Iowa Code (2011).

3. Worker's Compensation Insurance:

Workers' Compensation as provided by Chapter 85, Iowa code (2011).

H. Consultant shall be responsible and agrees to pay for any and all claims for wrongful death, personal injury, or property damage directly resulting from the negligence of

the Consultant, its officers, employees and agents, and arising from activities under this Agreement to the full extent permitted by Chapter 669, Code of Iowa (2011), which is the exclusive remedy for processing tort claims against the State of Iowa.

- I. Consultant is a "hybrid entity" as defined in the Health Insurance Portability and Accountability Act, 45 CFR §164.103, and will abide by the rules and regulations set forth in 45 CFR Parts 160 and 164 (HIPAA), as amended by the Health Information Technology for Economic and Clinical Health (HITECH) Act §§ 13400-13424, 42 U.S.C. §§ 17921-17954 (2009).

II. STATE

- A. State will pay Consultant, upon State's satisfaction for services of specimen storage and destruction have been completed, up to \$1 / specimen.
- B. State will not pay Consultant expenses as a separate item.
- C. TOTAL CONTRACT AMOUNT (Not to Exceed) \$40,500.00. Payment will be made consistent with SDCL Ch. 5-26.
- D. State will not be held liable for reimbursement of amounts shown on an itemized billing if not received within 30 calendar days from the close of the month being reported.

III. OTHER PROVISIONS

- A. SOVEREIGNTY AND IMMUNITY CLAUSE. Both parties to this agreement recognize the sovereignty of the other and the immunities inherent with such sovereignty. Nothing in this agreement shall be construed as an indemnification by one party of the other for the liabilities, acts, or omissions of the other party or third persons arising out of this agreement. Liability for the acts or omissions of the parties, their employees, agents, contractors, assigns, or other third persons arising out of and during this agreement shall be determined according to applicable law, subject to all available defenses and immunities.
- B. INTEGRATION. This contract is a complete version of the entire agreement between the parties with respect to the subject matter within this contract and supersedes all prior or contemporaneous written or oral understandings, agreements and communications between them with respect to such subject matter. This contract may be modified or amended only by a writing signed by both parties.
- C. TERMINATION: This contract may be terminated by either party hereto upon one hundred eighty (180) days written notice, and may be terminated by State for cause at any time, with or without notice.
- D. NOTICE: Any notice or other communication required under this contract shall be in writing and sent to the address set forth above. Notices shall be given by and to the State Contact Person on behalf of State, and by and to the Consultant Contact Person on behalf of Consultant, or such authorized designees as either party may from time to time designate in writing. Notices or communications to or between the parties shall be deemed to have been delivered when mailed by first class mail, provided that notice of default or termination shall be sent by registered or certified mail, or, if personally delivered, when received by such party.
- E. CERTIFICATION REGARDING DEBARMENT, SUSPENSION, INELIGIBILITY, AND VOLUNTARY EXCLUSION: Consultant agrees that neither Consultant, nor any of Consultant's principals is presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in transactions by any Federal department



or agency. Consultant will provide immediate written notice to the Department of Health, Division of Administration (600 East Capitol Avenue, Pierre, SD 57501 (605) 773-3361), if Consultant, or any of Consultant's principals, becomes debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in transactions involving Federal funding. Consultant further agrees that if this contract involves federal funds or federally mandated compliance, then Consultant is in compliance with all applicable regulations pursuant to Executive Order 12549, including Debarment and Suspension and Participants' Responsibilities, 29 C.F.R. § 98.510 (1990).

- F. **FUNDING TERMINATION:** This contract depends upon the continued availability of appropriated funds and expenditure authority from Congress, the Legislature or the Executive Branch for this purpose. This contract will be terminated for cause by State if Congress, the Legislature or Executive Branch fails to appropriate funds, terminates funding or does not grant expenditure authority. Funding termination is not a default by State nor does it give rise to a claim against State.
- G. **NONASSIGNMENT/SUBCONTRACTING:** Consultant shall not assign this contract, or any portion thereof, without the prior written consent of State. Consultant's assignment or attempted assignment of this contract, or any portion thereof, without State's prior written consent constitutes a material breach of contract. The Consultant may not use subcontractors to perform the services described herein without the express prior written consent of State. Consultant will include provisions in its subcontracts requiring its subcontractors to comply with the applicable provisions of this Agreement, to indemnify the State, and to provide insurance coverage in a manner consistent with this Agreement. Consultant will cause its subcontractors, agents, and employees to comply with applicable federal, state and local laws, regulations, ordinances, guidelines, permits and requirements and will adopt such review and inspection procedures as are necessary to assure such compliance.
- H. **FEDERAL AND STATE LAWS:** Consultant agrees that it will comply with all federal and state laws, rules and regulations as they may apply to the provision of services pursuant to this contract, including the Americans with Disabilities Act (ADA) of 1990, 42 U.S.C. §§ 12101-12213, and any amendment thereto, Section 306 of the Clean Air Act, and Section 508 of the Clean Water Act. Both parties further agree to provide services covered by this contract without regard to race, color, national origin, sex, age or disability as prohibited by state or federal law.
- I. **OWNERSHIP:** All reports, recommendations, documents, drawings, plans, specifications, technical data and information, copyrights, patents, licenses, or other products produced as a result of the services rendered under this contract, excluding medical records kept in the normal course of Consultant's business, will become the sole property of State. State hereby grants Consultant the unrestricted right to retain copies of and use these materials and the information contained therein in the normal course of Consultant's business for any lawful purpose. Either the originals, or reproducible copies satisfactory to State, of all technical data, evaluations, reports and other work product of Consultant shall be delivered to State upon completion or termination of services under this contract.
- J. **REPORTING OF PERSONAL INJURIES AND/OR PROPERTY DAMAGE:** Consultant agrees to report promptly to State any event encountered in the course of performance of this contract which results in injury to the person or property of third parties, or which may otherwise subject Consultant or State to liability. Reporting to State under this section does not satisfy Consultant's obligation to report any event to law enforcement or other entities as required by law.
- K. **SEVERABILITY:** In the event that any term or provision of this contract shall violate any applicable law, such provision does not invalidate any other provision hereof.
- L. **AUDIT REQUIREMENTS:**
In accordance with OMB Circular A-133, in the performance of services under this Agreement, Contractor shall be considered as a vendor and is not subject to the A-133 audit requirements or compliance with the federal cost principles of OMB Circular A-21. Payments to Contractor hereunder shall not be considered as Federal awards.
- M. **PERSONNEL:** Neither the Consultant nor any employee or agent thereof will hold him or herself out as or claim to be an officer or employee of State and will not make any claim, demand or application to or for any right or privilege applicable to an officer or employee of State including, but not limited to, workers' compensation, health, life, malpractice insurance, and retirement membership or credit.
- N. **FORCE MAJEURE:** Neither Consultant nor State shall be liable to the other for any delay in, or failure of performance of, any covenant or promise contained in this contract, nor shall any delay or failure constitute default or give rise to any liability for damages if, and only to the extent that, such delay or failure is caused by "force majeure". As used in this contract, "force majeure" means acts of God, acts of the public enemy, acts of the State and any governmental entity in its sovereign capacity, fires, floods, epidemics, quarantine restrictions, strikes or other labor disputes, freight embargoes, or unusually severe weather.
- O. **CONTRACT ORIGINAL AND COPIES:** An original of this contract will be retained by the State Auditor's Office. A photocopy will be on file with the South Dakota Department of Health and a second original will be sent to Consultant.
- P. **RECORD RETENTION/EXAMINATION:** Consultant agrees to maintain all records that are pertinent to this contract and retain them for a period of three years following final payment against the contract. State agrees to assume


responsibility for these items after that time period. These records shall be subject at all reasonable times for inspection, review or audit by State, other personnel duly authorized by State, and federal officials so authorized by law.

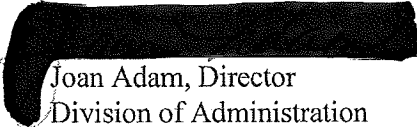
- Q. DRUG FREE WORK PLACE: Consultant agrees to encourage all its employees to refrain from using illegal drugs which may affect an employee's ability to perform the essential functions required under the terms and conditions of this contract. State reserves the right to terminate this contract if Consultant, or any of its employees or agents, is convicted of using illegal drugs. Consultant further agrees that if this contract involves federal funds or federally mandated compliance, then Consultant is in compliance with the requirements of the "Drug-Free Workplace Act" (Public Law 100-690 Title V, Subtitle D, 41 U.S.C. §§ 701 et seq.).
- R. LOBBYING: Consultant agrees to not use any of the funds received pursuant to this contract for lobbying purposes. Consultant further agrees that if this contract involves federal funds or federally mandated compliance, the Consultant is in compliance with all applicable regulations pursuant to Section 319 of Public Law 101-121, Guidance for New Restrictions on Lobbying, including Certification and Disclosure, 29 C.F.R. § 93.110 (1990).
- S. RECYCLING. State strongly encourages Consultant to establish a recycling program to help preserve our natural resources and reduce the need for additional landfill space.

The parties signify their agreement by signing below.

	<u>6/25/12</u>	_____	_____
Colleen Winter, Director Health and Medical Services Department of Health	Date	Consultant Signature	Date
			<u>6/20/12</u>

Jennifer Lassner
Jennifer Lassner
Executive Director
Division of Sponsored Programs

	<u>6/20/12</u>
Kari J. Weisbeck Administrator, Financial Management Department of Health	Date


Joan Adam, Director
Division of Administration
Department of Health

6-27-12
Date

State Contact Person: Lucy Fossen

Phone: (605) 773-2944

Consultant Contact Person: Loren LeClair

Phone: (319) 335-2120

The following shall be completed by the Consultant:

Nonprofit Profit
Consultant fiscal year beginning _____ and ending _____

The following shall be completed by the State:

Subrecipient status _____ OR Vendor status _____
MSA Account code 5204 _____

Fund Source Name:	Fund Source Name:	Fund Source Name:
CFDA No:	CFDA No:	CFDA No:
Program:	Program:	Program:
CO: 2018-Federal	CO: 2018-Federal	CO: 2018-Federal
3047-Other	3047-Other	3047-Other
1000-General	1000--General	1000-General

SDCL 1-24A-1 states that a copy of all consulting contracts shall be filed by the agency with the State Auditor within five days after such contract is entered into and finally approved by the contracting parties. For further information about consulting contracts, see the State Auditor's policy handbook.

06-12-12-02

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STATE OF SOUTH DAKOTA
FEE SCHEDULE
ATTACHMENT A-1, June 1, 2012 thru May 31, 2017

Consultant will provide laboratory services under hit contract for the following fees:

\$65.00 per initial* specimen

Which includes:

\$48.50 for basic NBS laboratory services

\$11.50 for Courier transport of NBS specimens for SD birthing facilities to the SHL NBS
Laboratory in Ankeny IA.

\$5.00 for short term follow-up services.

Annual reassessment of fee is permissible.

*There will be no fee charged for any subsequent ("repeat") NBS specimen requested by SHL for the purpose of obtaining a valid screen result or resolving an abnormal screen result.