

MEMO

To: Carol Sitko
From: Anita Smith asj
Subject: Contract Document
Date: 6/16/04

RECEIVED
04 JUN 16 PM 1:37
PUBLIC HEALTH LABORATORY

Your contract document is being returned for the following reasons:

The certification is fully signed and you may now start the contract for encumbrance.
• Keep a copy of the approved/signed certification for your file and send original Cert and **1 copy** of the contract to me for encumbrance along with a completed encumbrance worksheet. (all waivers/paperwork)

The contract has been encumbered.
• Send **4 copies** of the contract to the contractor for signature and return the 4 signed copies along with the **signed certification** copy to me for further processing. (and any other paperwork ie; single source, RFP etc)

The contract needs a late letter (16a16c.wpd) included. This form may be obtained in the intranet web site, <http://www.md.admin.state.mn.us/mn05002.htm>.
• Return the contract, signed late letter, and the certification to me for further processing.

The contract/amendment/work order has been fully executed.
• Keep one copy for your files and send the contractor 1 copy.

Other

If you have any questions regarding your contract, please e-mail or call me.

Anita Smith
Encumbrance Monitor
Minnesota Dept of Health
Financial Management
400-Golden Rule
85 E Seventh Place
St. Paul, MN 55101
Phone-651-215-0670 fax-651-296-5276 e-mail-anita.smith@health.state.mn.us

COPY

STATE OF MINNESOTA ENCUMBRANCE WORKSHEET

State Accounting Information:

CFMS Contract No. _____

Agency Contract Identification No.: A61671

Agency: Health H12	Fiscal Years: 2004-2009 (See Next Page for breakdown)	Vendor Number: 200515190 00
Total Amount of Contract: \$6,985.000	Amount of Contract First FY: 579,835	
Commodity Code: 040 02	Commodity Code:	Commodity Code:
Object Code: 2D50	Object Code:	Object Code:
Amount:	Amount:	Amount:
Accounting Distribution 1: FY 04	Accounting Distribution 2: FY 05	Accounting Distribution 3: FY 06
Fund: 170	Fund: 170	Fund: 170
Appr: 173	Appr:	Appr:
Org/Sub: 4110	Org/Sub: 4110	Org/Sub: 4110
Rept Catg:	Rept Catg:	Rept Catg:
Amount: \$579,835.00	Amount: \$1,391,600.00	Amount: \$1,391,600.00
Accounting Distribution 4: FY 07	Accounting Distribution 5: FY08	Accounting Distribution 6: FY 09
Fund: 170	Fund: 170	Fund: 170
Appr:	Appr:	Appr:
Org/Sub: 4110	Org/Sub: 4110	Org/Sub: 4110
Rept Catg:	Rept Catg:	Rept Catg:
Amount: \$1,391,600.00	Amount: \$1,391,600.00	Amount: 838,765.00

Contract Start Date: June 14, 2004

Expiration Date: September 30, 2008

Contractor Name and Address: Mayo Collaborative Services, Inc. d/b/a Mayo Medical Laboratories, Rochester, MN, 150 ~~Third~~ Street SW, Rochester, MN 55902, Contact: Frank Ray, 507-284-8738.

Social Security No. or Federal Employer I.D. No.: 41-1346366

Minnesota Tax I.D. No. (if applicable): _____

**This Page Contains Private Data
Do Not Circulate
DO NOT REPRODUCE
OR DISTRIBUTE EXTERNALLY WITHOUT EXPRESS
WRITTEN PERMISSION OF THE CONTRACTOR.**

**STATE OF MINNESOTA
PROFESSIONAL AND TECHNICAL SERVICES CONTRACT**

This contract is between the State of Minnesota, acting through its Commissioner of the Minnesota Department of Health (the "State" or "MDH") and Mayo Collaborative Services, Inc. d/b/a Mayo Medical Laboratories, Rochester, MN, a Minnesota corporation ("Contractor") with a principle place of business located at Stabile Building, 150 Third Street, S.W., Rochester, MN 55902.

Recitals

1. The State, through MDH, screens all infants born in Minnesota for heritable and congenital disorders pursuant to Minnesota Statutes Sections 144.125 to 144.128 so that such disorders may be identified and treated soon after birth, avoiding developmental disabilities and death.
2. Pursuant to Minn. Stat. § 15.061 and §144.0742, MDH is empowered to engage such assistance as deemed necessary to carry out its obligations;
3. The State is in need of assistance in the screening of all infants born in Minnesota for heritable and congenital disorders; and
4. Contractor has extensive and unique expertise in the use of the tandem mass spectrometry instrumentation for newborn screening.

Contract

1 Term of Contract

- 1.1 **Effective Date.** June 14, 2004, or the date the State obtains all required signatures under Minnesota Statutes § 16C.05, subdivision 2, whichever is later. **The Contractor shall not begin work under this Agreement until this Agreement is fully executed and the Contractor has been notified by the State's Authorized Representative to begin the work.**
- 1.2 **Expiration Date:** September 30, 2008, or until all obligations have been satisfactorily fulfilled or this Agreement is terminated in accordance with Section 15 below, whichever occurs first.
- 1.3 **Survival of Terms.** The following clauses survive the expiration or cancellation of this Agreement: 8. Liability; 9. State Audits; 10. Government Data Practices and Intellectual Property; 12. Publicity and Endorsement; 13. Governing Law, Jurisdiction, and Venue; and 14. Data Disclosure.
- 1.4 **Effect of Termination.** Upon termination of this Agreement, Contractor shall work cooperatively with the State to facilitate the transfer of newborn screening services as described more fully at 15.1.

2 Contractor's Duties

- 2.1 **Testing Services.** Contractor will perform newborn screening (approximately 70,000 per year) using tandem mass spectrometry for certain inborn errors of metabolism as listed on Exhibit 2.1 and incorporated herein by reference (the "Newborn Screening Services"). Contractor will analyze acylcarnitines and amino acids in dried blood spots by tandem mass spectrometry and perform second-tier analysis using blood from the same newborn screening card if indicated by results of acylcarnitine and amino acid analysis. Accessioning (for filter cards processed by St. Mary's Hospital or Rochester Methodist Hospital), analysis and reporting will occur within 24 (twenty four) hours of receipt of the specimens by Contractor in Rochester. Newborn screening services shall be provided in accordance with the terms of this Agreement and the guidelines and notices set forth in the most current edition of the *Mayo Medical Laboratories Test Catalog*.
- 2.2 **Specimens.** Contractor shall provide or arrange for the provision of courier services for the transport of specimens from MDH at 717 Delaware St. S.E., Minneapolis, MN 55414 or from the future location of MDH to the Contractor, Monday through Saturday, once daily at a time mutually agreed to by the parties. Specimens arriving at MDH from birthing centers will be logged in by the State and the filter cards will be split by the State for analysis prior to pick up by Contractor's couriers. MDH shall promptly process specimens so that the time between receipt and send out to Contractor shall not exceed 24 (twenty four) hours. The State will promptly notify Contractor of any change in the address of MDH facilities.
- 2.3 **Computer Services.** Contractor shall furnish and install at MDH the MayoLink software and two barcode printers for the requesting of Newborn Screening Services and reporting of results by Contractor. Contractor will provide application support for MayoLink. The MayoLink web-based application can run on existing MDH computers and printers that meet the minimum hardware requirements. Contractor will provide these computer services at no additional charge while this Agreement is in effect.
- 2.4 **Result Reporting.** All results of Newborn Screening Services provided by Contractor shall be transmitted to the State electronically via MayoLink. In the event an abnormal result is obtained by Contractor, Contractor shall make every effort to immediately contact the hospital or primary care provider, fax the results to the hospital or primary care provider and offer advice or contact information regarding metabolic or other specialists in the birthing center's service area. Contact information for relevant specialists will be developed and maintained by MDH for distribution to physicians by Contractor. Contractor shall notify the on-call metabolic specialist and his or her designee at the University of Minnesota and at Mayo of such abnormal results to the extent necessary to provide follow up emergency care. Contractor shall email a follow up report to the State regarding actions taken on the abnormal result.
- 2.5 **Mayo Patients.** For filter cards processed by St. Marys Hospital or Rochester Methodist Hospital, the filter cards will be sent directly to Contractor for testing rather than to MDH. Contractor will split the filter cards, provide MDH with its portion of the filter cards and the newborn screening tests and report results to MDH as required under 2.4
- 2.6 **Recommendations for Follow up of Abnormal Results.** Reports to the State on initial testing by Contractor may include one or more recommendations for follow up. Follow up testing is not within the scope of the services covered by this Contract and the costs of such testing shall not be included on Contractor's invoices submitted to the State.

- 2.7 **Second Tier Testing for Congenital Adrenal Hyperplasia ("CAH").** The State shall perform the initial screen for CAH on all specimens. Contractor shall perform second-tier testing of dried blood spot specimens for CAH within twenty-four hours of receipt of an abnormal result notification for 17-OHP from the State. Contractor shall perform an analysis of the patient's newborn screening card sent to Contractor for 17-OHP, androstendione and cortisol by LC-MS/MS. Second-tier testing by LC-MS/MS shall prevent the necessity of additional sample collection and testing when a normal result is obtained by LC-MS/MS. The State shall issue a preliminary report to the treating physician indicating the abnormal result and the fact that additional investigations are pending to facilitate more rapid treatment initiation of symptomatic newborns. The Testing Fee at 4.1.1 was calculated based on current clinical processes and historical reference range cut-off points, as well as an assumption that no more than 1(one) percent of babies will have a positive result requiring CAH follow up. If greater than 2 (two) percent of babies per year require CAH follow up, those tests will be provided by Contractor but the fees will be renegotiated independent of the terms of this Agreement.
- 2.8 **Quality Control and Assurance.** Contractor may utilize unidentified specimens or data for quality control purposes, calibration of testing methodology, methods validation, and test development, provided that all such specimens must be unidentified in a manner that is approved by the State and that Contractor complies with the destruction requirements of Minn. Stat. §144.125 subd. 3.
- 2.9 **Inclusion of Additional Disorders.** The inclusion of additional disorders to the Newborn Screening Program must be recommended to the State via the Newborn Screening Advisory Committee and be consistent with criteria established in Minnesota Statutes §§144.125 to 144.128, as amended. Exhibit 2.1 and the Testing Fee may be amended upon the mutual written agreement of the parties to include those additional disorders recommended by the Newborn Screening Advisory Committee.
- 2.10 **Ownership, Control, Storage, and Disposal of the Dried Blood Spots.** The Contractor hereby acknowledges that all dried blood spot ("Newborn Screening" or "NBS") specimens tested pursuant to this Agreement belong to the State. After the completion of testing by Contractor, the NBS card with leftover dried blood will be securely kept and stored by Contractor for a period of at least two years, unless the parents opt to have the dried blood specimens destroyed sooner as permitted by Minn. Stat. §144.125 subd. 3. The State will notify the Contractor in writing of such individual request, and Contractor shall promptly destroy the specimen. If no request for destruction is received, the NBS card with residual dried blood will be destroyed by Contractor in accordance with its usual and customary specimen retention and destruction policies.
- 2.11 **Use of Specimens or Data for Research.** Any request to use unidentified specimens or data for purposes other than those listed in section 2.8 requires the written authorization of Contractor's Institutional Review Board, the State's Authorized Representative and MDH's Institutional Review Board, and any other individual consents as required by law. Requests must specify, at a minimum, how Contractor will unidentify specimens or data and how Contractor will comply with the parent's wishes for the destruction of the specimens or data. No identifiable specimens or data may be used for research without the written authorization of the State's Authorized Representative, the Institutional Review Boards of MDH and Contractor and the written consent of the subject's parent or legal guardian.
- 2.12 **Compliance and Data Security.** The Contractor shall comply with all applicable laws, regulations and standards applicable to the provision of Newborn Screening Services and operation of clinical laboratories, including but not limited to the Clinical Laboratory Improvement Act("CLIA"), 42 U.S.C. §263a and all regulations promulgated thereunder. All interactions between Contractor and MDH are subject to and must meet or exceed all state, federal and industry regulations. The parties shall execute any and all additional documents necessary for each to comply with their respective data privacy obligations.

2.13 **Program Evaluation.** MDH and appropriate representatives of Contractor will participate in the design of a system for evaluating the success of the Newborn Screening Program Newborn Testing Services. Performance indicators will include, but not be limited to the following:

- False positive rate with and without second tier testing for 17-OHP.
- Cost savings resulting from a reduction in abnormal 17-OHP results.
- Achievement of universal screening.
- Efficiency Measures:
 - Time to analysis from collection to the laboratory, MDH and Mayo
 - Time to report from delivery to laboratory to release of report
 - Time to laboratory follow up for additional specimens obtained from abnormal cases
 - Time to clinical evaluation of abnormal cases
 - Time to treatment for positive cases
- Decline in state infant mortality (limited to SIDS/sudden unexpected death)

2.14 **Program Governance.** MDH will establish a committee to guide Contractor and MDH program interaction, and to anticipate and respond to issues related to the provision of Newborn Screening Services. A committee will be identified to include both MDH and Contractor representatives that will meet at least quarterly to discuss program issues and to evaluate Contractor's performance.

3 **Time.** The Contractor and MDH must comply with all time requirements described in this contract. In the performance of this Contract, time is of the essence.

4 **Consideration and Payment.**

4.1 **Consideration.** The State will pay for all services performed by the Contractor under this Agreement as follows:

- (A) **Compensation.** The Contractor will be paid \$19.88 per NBS specimen tested (the "Testing Fee"). It is anticipated that Contractor will receive approximately 70,000 specimens per year.
- (B) **Total Obligation.** The total obligation of the State for all compensation and reimbursements to Contractor shall not exceed \$6,985,000. The total obligation of MCSI for the maximum number of NBS specimens tested shall not exceed 351,358.

4.2 **Payment**

- (A) **Invoices.** The State will promptly pay the Contractor after the Contractor presents an itemized invoice for the services actually performed and the State of Minnesota's Authorized Representative accepts the invoiced services. Invoices must be submitted timely and according to the following schedule:

The Contractor will submit monthly invoices to the State listing the number of newborns screened and the applicable Testing Fees. Within thirty (30) days of receipt of the invoice, the State's Authorized Representative shall either accept or reject the invoice, and the State shall pay the amount owed.

5 Conditions of Payment

All services provided by the Contractor under this Agreement must be performed to the State's satisfaction, as determined at the sole discretion of the State's Authorized Representative and in accordance with all applicable federal, state, and local laws, ordinances, rules, and regulations. The Contractor will not receive payment for work found by the State to be unsatisfactory or performed in violation of federal, state, or local law. Notwithstanding the foregoing, the State shall not unreasonably withhold its approval of Contractor's services.

6 Authorized Representatives

The parties' authorized representatives (each an "Authorized Representative") are identified as follows and may be changed at any time upon written notice to the other party:

- 6.1 **State.** The State's Authorized Representative is Christine Everson, Assistant Director of the Public Health Laboratory Division, 717 Delaware St. S.E., Minneapolis, MN 55414, (612) 676-5384, or her successor, and the State's Authorized Representative has the responsibility to monitor the Contractor's performance and the authority to accept the services provided under this Agreement. If the services are satisfactory, the State's Authorized Representative will certify acceptance on each invoice submitted for payment.
- 6.2 **Contractor.** The Contractor's Authorized Representative is Frank Ray, Administrator MCSI, Mayo Collaborative Services, Inc., Stabile Building, 150 Third St, S.W., Rochester, MN 55902, (507) 284-8738, or his successor. If the Contractor's Authorized Representative changes at any time during the term of this Agreement, the Contractor must immediately notify the State.

7 Assignment, Amendments, Waiver, and Contract Complete.

Neither party may assign or transfer any rights or obligations under this Agreement without the prior consent of the other party and a fully executed Assignment Agreement, executed and approved by the same parties who executed and approved this Agreement, or their successors in office. For example, Contractor may not contract with any outside organization to perform any of its testing or data management responsibilities under this contract. Any amendment to this Agreement must be in writing and will not be effective until it has been executed and approved by the same parties who executed and approved the original Agreement, or their successors in office. If either party fails to enforce any provision of this Agreement, that failure does not waive the provision or its right to enforce it. This Agreement contains all negotiations and agreements between the State and the Contractor. No other understanding regarding this Agreement, whether written or oral, may be used to bind either party.

8 Liability

The Contractor must indemnify, save, and hold the State, its agents and employees harmless from any claims or causes of action, including attorney's fees incurred by the State, arising from the negligent or wrongful acts of the Contractor or the Contractor's agents or employees under this Agreement. This clause will not be construed to bar any legal remedies either party may have for the other party's failure to fulfill its obligations under this Agreement.

9 State Audits

Under Minn. Stat. § 16C.05, subd. 5, Contractor's books, records, documents, and accounting procedures and practices relevant to this Agreement are subject to examination by the State and/or the State Auditor or Legislative Auditor, as appropriate, for a minimum of six years from the end of this Agreement.

10 Government Data Practices and Intellectual Property.

10.1 **Government Data Practices.** The Contractor, to the extent required by Minn. Stat. §13.05, subs. 6 and 11, and State must comply with the Minnesota Government Data Practices Act, Minn. Stat. Ch. 13, with respect to all data provided by the State to the Contractor under this Agreement and with respect to all data created, collected, received, stored, used, maintained, or disseminated by the Contractor under this Agreement.

If the Contractor receives a request to release the data referred to in this Clause, other than a request from the individual subject of the data or a minor subject's parent or guardian, the Contractor must immediately notify the State. The State will subsequently give the Contractor instructions concerning the release of the data to the requesting party. The Contractor will follow these instructions when releasing the data.

10.2 **Newborn Screening Data.** The newborn screening data provided by State to Contractor under this Agreement includes private data under Minn. Stat. § 13.3805. With respect to the newborn screening data provided by State under this Agreement and the test results created by Contractor under this Agreement:

- (A) State shall own the data;
- (B) Contractor shall store the data on behalf of the State at the highest level of confidentiality, consistent with state and federal laws and standards in the industry;
- (C) Contractor shall access, use and disclose the data only to perform Contractor's duties under this Agreement or for quality or research purposes to the extent permitted at 2.8 and 2.10, except that Contractor may share the data with the individual subject of the data or a minor subject's parent or guardian or as otherwise required by law;
- (D) Contractor shall ensure that the data, while maintained by Contractor in any form, cannot be accessed by any individual who is not employed by Contractor;
- (E) Contractor shall, on written request from State, promptly destroy the test results of an individual patient pursuant to a parent request under Minn. Stat. 144.125, subd. 3; and
- (F) Contractor shall, at the expiration or termination of this contract, make reasonable efforts to destroy or return to the State all records of test results generated under this Agreement. If destruction or return of the test results cannot be accomplished through commercially reasonable means, then Contractor shall restrict access to the test results to the greatest extent possible

10.3 **Nonidentifiable Newborn Screening Data.** Notwithstanding Section 10.2 of this Agreement, Contractor may release newborn screening data in a form that does not identify any individual, and that does not allow anyone to identify any individual who is a subject of the newborn screening data. The Contractor must use a statistically valid, HIPAA compliant method to de-identify the records. Before releasing de-identified data, Contractor will give a copy to the state for the sole purpose of the State reviewing to ensure that no individual subject of the newborn screening data can be identified. The State shall respond promptly. If no comment or objection is received by the Contractor within thirty (30) calendar days after submission to the State, Contractor may proceed to release the de-identified data.

10.4 Intellectual Property Rights.

- (A) The parties agree that Contractor owns all rights, title, and interest in the intellectual property rights, including copyrights, patents, trade secrets, trademarks, and service marks in any Works and Documents created by the Contractor and paid for under this Agreement. The Contractor is solely responsible for costs involved in patent application and prosecution and registration of any copyrights, trademarks or servicemarks.

Contractor grants to State an irrevocable, royalty-free, non-exclusive license right to use such Works and Documents for the sole purpose of processing Minnesota newborn screening specimens and carrying out the testing services defined in part 2.1 under this Agreement at the State's facilities. Any inventions and trade secrets (e.g. protocols, cut-off values, tests, sample preparation procedures, statistical algorithms) created by the Contractor and paid for under this Agreement will be made available to MDH, without license or royalty, for use in the testing of Minnesota NBS specimens.

"Works" shall mean all inventions, improvements, discoveries (whether or not patentable), computer programs, reports, notes, studies, photographs, negatives, designs, drawings, specifications, materials, tapes, and disks conceived, reduced to practice, created or originated by the Contractor in the performance of this Agreement. "Works" does not include any specimens or newborn screening test results, which are the exclusive property of the State.

Works shall include "Documents." "Documents" are the originals of any databases, computer programs, reports, notes, studies, photographs, negatives, designs, drawings, specifications, materials, tapes, disks, or other materials, whether in tangible or electronic forms, prepared by the Contractor in the performance of this Agreement. The Documents conceived, reduced to practice, created or originated by the Contractor in the performance of this Agreement will be the exclusive property of Contractor and must be immediately returned to Contractor by the State upon completion or cancellation of this Agreement, except to the extent that their retention by the State is necessary for the State's exercise, use and enjoyment of the licenses and rights to use granted to the State by the Contractor herein.

The State assigns all right, title, and interest it may have in the Works and the Documents to Contractor. The State must, at the request of Contractor, execute all papers and perform all other acts necessary to transfer or record Contractor's ownership interest in the Works and Documents.

- (B) Any article, interpretation or other public use of the data related to the work performed under this Agreement for purposes of publication or other scholarly activity must be mutually agreeable to and approved by the Contractor and the State prior to publication or use. If no comments or objections are received within ninety (90) calendar days after submission to the other party, the submitting party may proceed to publish or use such materials. The parties will not unreasonably withhold authorization for publication. This paragraph does not apply to information given to the Legislature, the media, or the public at large in ways that are typical in government agency communications.
- (C) Works and Documents independently created by the State are not subject to part 10(A) or 10(B).

11 Workers' Compensation

The Contractor certifies that it is in compliance with Minn. Stat. § 176.181, subd. 2, pertaining to workers' compensation insurance coverage. The Contractor's employees and agents will not be considered State employees. Any claims that may arise under the Minnesota Workers' Compensation Act on behalf of these employees or agents and any claims made by any third party as a consequence of any act or omission on the part of these employees or agents are in no way the State's obligation or responsibility.

12 Publicity, Endorsement and Use of Name

12.1 **Publicity.** Any publicity regarding the subject matter of this Agreement must identify the State as the sponsoring agency and must not be released without prior written approval from the State's Authorized Representative. For purposes of this provision, publicity includes notices, informational pamphlets, press releases, research, reports, signs, and similar public notices prepared by or for the Contractor individually or jointly with others, or any subcontractors, with respect to the program, publications, or services provided resulting from this Agreement.

12.2 **Endorsement.** The Contractor must not claim that the State endorses its products or services.

12.3 **Use of Name.** Where appropriate, State will obtain prior approval from Contractor before using Contractor's name or trademark in promotional, descriptive, or informational materials concerning newborn screening services in Minnesota.

13 Governing Law, Jurisdiction, and Venue.

Minnesota law, without regard to its choice-of-law provisions, governs this Agreement. Venue for all legal proceedings out of this contract, or its breach, must be in the appropriate state or federal court with competent jurisdiction in Ramsey County, Minnesota.

14 Data Disclosure

Under Minn. Stat. § 270.66, and other applicable law, the Contractor consents to disclosure of its federal employer tax identification number, and/or Minnesota tax identification number, already provided to the State, to federal and state agencies and state personnel involved in the payment of state obligations. These identification numbers may be used in the enforcement of federal and state laws which could result in action requiring the Contractor to file state tax returns, pay delinquent state tax liabilities, if any, or pay other state liabilities.

15 Termination

15.1 **By Either Party.** Either party may cancel this Agreement at any time, with or without cause, upon thirty (30) days' written notice to the other party. Upon termination, the Contractor will be entitled to payment, determined on a pro rata basis, for services satisfactorily performed prior to termination. Contractor shall continue to provide services under this Agreement during the notice period. If Contractor does not provide NBS specimen testing during the notice period, Contractor shall pay State \$19.88 for each NBS specimen not analyzed. If necessary due to personnel turnover at State, in the event of termination by Contractor, Contractor will work cooperatively with State to provide training and consulting for up to a thirty (30) day period to help ensure the transition and operation of NBS testing back to the State or other contracting party. Contractor will provide training and consulting subject to third party obligations that prohibit or limit the transfer of intellectual property.

15.2 **Termination for Insufficient Funding.** The State may immediately terminate this agreement if it does not obtain funding from the Minnesota Legislature, or other funding source; or if funding cannot be continued at a level sufficient to allow for the payment of the services covered here. Termination must be by written or fax notice to the Contractor. The State is not obligated to pay for any services that are provided after notice and effective date of termination. However, the Contractor will be entitled to payment, determined on a pro rata basis, for services satisfactorily performed before the effective date of termination. The State will not be assessed any penalty if this Agreement is terminated because of the decision of the Minnesota Legislature, or other funding source, not to appropriate funds. The State must provide the Contractor notice of the lack of funding within a reasonable time of the State's receiving that notice.

16 No Discrimination.

Contractor shall comply with the provisions of Minn. Stat. § 181.59 which requires that:

Every contract for or on behalf of the state of Minnesota, or any county, city, town, township, school, school district, or any other district in the state, for materials, supplies, or construction shall contain provisions by which the contractor agrees: (1) That, in the hiring of common or skilled labor for the performance of any work under any contract, or any subcontract, no contractor, material supplier, or vendor, shall, by reason of race, creed, or color, discriminate against the person or persons who are citizens of the United States or resident aliens who are qualified and available to perform the work to which the employment relates; (2) That no contractor, material supplier, or vendor, shall, in any manner, discriminate against, or intimidate, or prevent the employment of any person or persons identified in clause (1) of this section, or on being hired, prevent, or conspire to prevent, the person or persons from the performance of work under any contract on account of race, creed, or color; (3) That a violation of this section is a misdemeanor; and (4) That this contract may be canceled or terminated by the state, county, city, town, school board, or any other person authorized to grant the contracts for employment, and all money due, or to become due under the contract, may be forfeited for a second or any subsequent violation of the terms or conditions of this contract.

17 Affirmative Action Requirements.

The State intends to carry out its responsibility for requiring affirmative action by its Contractors.

17.1 **Covered Contracts and Contractors.** If the Contract exceeds \$100,000 and the contractor employed more than 40 full-time employees on a single working day during the previous 12 months in Minnesota or in the state where it has its principle place of business, then the Contractor must comply with the requirements of Minn. Stat. § 363.073 and Minn. R. Parts 5000.3400-5000.3600. A contractor covered by Minn. Stat. § 363.073 because it employed more than 40 full-time employees in another state and does not have a certificate of compliance, must certify that it is in compliance with federal affirmative action requirements.

17.2 **Minn. Stat. § 363.073.** Minn. Stat. § 363.073 requires the Contractor to have an affirmative action plan for the employment of minority persons, women, and qualified disabled individuals approved by the Minnesota Commissioner of Human Rights ("Commissioner") as indicated by a certificate of compliance. The law addresses suspension or revocation of a certificate of compliance and contract consequences in that event. A contract awarded without a certificate of compliance may be voided.

17.3 Minn. R. 5000.3400-5000.3600.

- (A) **General.** Minn. R. 5000.3400-5000.3600 implements Minn. Stat. § 363.073. These rules include, but are not limited to, criteria for contents, approval, and implementation of affirmative action plans; procedures for issuing certificates of compliance and criteria for determining a contractor's compliance status; procedures for addressing deficiencies, sanctions, and notice and hearing; annual compliance reports; procedures for compliance review; and contract consequences for non-compliance. The specific criteria for approval or rejection of an affirmative action plan are contained in various provisions of Minn. R. 5000.3400-5000.3600 including, but not limited to, parts 5000.3420-5000.3500 and 5000.3552-5000.3559.
- (A) **Disabled Workers.** The Contractor must comply with the following affirmative action requirements for disabled workers.
- (1) The Contractor must not discriminate against any employee or applicant for employment because of physical or mental disability in regard to any position for which the employee or applicant for employment is qualified. The Contractor agrees to take affirmative action to employ, advance in employment, and otherwise treat qualified disabled persons without discrimination based upon their physical or mental disability in all employment practices such as the following: employment, upgrading, demotion or transfer, recruitment, advertising, layoff or termination, rates of pay or other forms of compensation, and selection for training, including apprenticeship.
 - (2) The Contractor agrees to comply with the rules and relevant orders of the Minnesota Department of Human Rights issued pursuant to the Minnesota Human Rights Act.
 - (3) In the event of the Contractor's noncompliance with the requirements of this clause, actions for noncompliance may be taken in accordance with Minnesota Statutes Section 363.073, and the rules and relevant orders of the Minnesota Department of Human Rights issued pursuant to the Minnesota Human Rights Act.
 - (4) The Contractor agrees to post in conspicuous places, available to employees and applicants for employment, notices in a form to be prescribed by the commissioner of the Minnesota Department of Human Rights. Such notices must state the Contractor's obligation under the law to take affirmative action to employ and advance in employment qualified disabled employees and applicants for employment, and the rights of applicants and employees.
 - (5) The Contractor must notify each labor union or representative of workers with which it has a collective bargaining agreement or other contract understanding, that the contractor is bound by the terms of Minnesota Statutes Section 363.073, of the Minnesota Human Rights Act and is committed to take affirmative action to employ and advance in employment physically and mentally disabled persons.
- (B) **Consequences.** The consequences for the Contractor's failure to implement its affirmative action plan or make a good faith effort to do so include, but are not limited to, suspension or revocation of a certificate of compliance by the Commissioner, refusal by the Commissioner to approve subsequent plans, and termination of all or part of this contract by the Commissioner or the State.
- (C) **Certification.** The Contractor hereby certifies that it is in compliance with the requirements of Minn. Stat. § 363.073 and Minn. R. 5000.3400-5000.3600 and is aware of the consequences for noncompliance.

- 18. Non-Exclusivity.** Contractor shall retain the full right and responsibility to establish, contract or otherwise associate with other government entities, laboratories, hospitals, health care entities, individual practice associations, health maintenance organizations, insurance companies, employers or other entities for furnishing clinical laboratory testing services without being deemed in contravention or breach of this Agreement or any other obligation to the State.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the date first above written.

1. STATE ENCUMBRANCE VERIFICATION

Individual certifies that funds have been encumbered as required by Minn. Stat. §§ 16A.15 and 16C.05.

Signed: Anto Smith

Date: 5/20/04

CFMS Contract No. A- 61671

2. CONTRACTOR

The Contractor certifies that the appropriate person(s) have executed the contract on behalf of the Contractor as

required by applicable articles, bylaws, resolutions, or ordinances.

By: [Signature]

Title: ADMINISTRATIVE DIRECTOR

Date: 6/2/04

By: _____

Title: _____

Date: _____

3. STATE AGENCY

By: [Signature]
(with delegated authority)

Title: DIRECTOR FINANCIAL MGT.

Date: 6/2/04

4. COMMISSIONER OF ADMINISTRATION

As delegated to Materials Management Division

By: Original signed
JUN 14 2004

Date: By Gerald T. Joyce

Distribution:
Agency
Contractor
State's Authorized Representative - Photo Copy

PROFESSIONAL/TECHNICAL CONTRACT CERTIFICATION FORM

Submit to: Department of Administration, Materials Management Division, Professional and Technical Service Contracts, 112 Administration Building, 50 Sherburne Avenue, St. Paul, MN 55155.

Certification Requirements: Required for all Professional/Technical Service Contracts, and Joint Powers Agreements in excess of \$5,000 (Minn. Stat. 16C.08). Agencies should submit TWO copies of this Contract Certification Form. When the Professional/Technical Service Contracts are estimated to be over \$50,000, submit two copies of this form with a copy of the *State Register* ad and a copy of your complete RFP.

Department Minnesota Department of Health	Division Public Health Laboratory
Estimated Cost: \$6,985,000	Source of Funds SGSR – Newborn Screening Fee
<p>*Original Contract Period: From: November 1, 2003 To: September 30, 2008 With option to extend ___ add'l ___ yr. periods</p> <p><small>*Note: According to Minn. Stat. 16C.08 Subd. 3(7), the combined contract and amendment cannot exceed five years, unless otherwise provided for by law. The term of the original contract must not exceed two years unless the commissioner determines that a longer duration is in the best interest of the state. If you are requesting that the original contract length be longer than two years, please write a justification below:</small></p> <p>It is essential that newborn screening continue uninterrupted. This partnership requires a long term commitment to measure its effectiveness. In addition, it is important to lock in the costs throughout the contract period to ensure the continued availability of funding for newborn screening.</p>	

Agency certifies that Minn. Stat. §16C.08 allows agency to enter into this professional/technical service contract. *(Please check with agency attorney general staff if in doubt.)*

Nature of Contract: *(Include a brief description of the service.)*

The Minnesota Department of Health screens all Minnesota newborns for heritable and congenital disorders. By treating these disorders soon after birth, development disabilities and death can be avoided.

The Minnesota Department of Health will contract with the Mayo Clinic's Biochemical Genetics Laboratory to conduct advanced newborn screening on all babies born in Minnesota. This contract provides for a public - private partnership that would enable the private sector to assist and enhance public health activities such as Minnesota's Newborn Screening Program.

The Mayo Clinic has extensive and unique expertise in the use of the tandem mass spectrometry instrumentation for newborn screening. The Mayo will screen all Minnesota newborns (approximately 70,000 per year) for over thirty heritable and congenital disorders using the advanced instrumentation called tandem mass spectrometry. Using alternative technology, MDH would adopt new screening tests for two added medical conditions and would continue to screen for four of the five currently screened disorders. MDH would continue responsibility for maintaining the statutory authority, setting and collecting fees, receiving and distributing specimens for analysis, notifying physicians of presumptive positive results, and assuring infants are connected with specialty care.

Product or Result: *(e.g., report with recommendations, plans and specifications, activity – give details.)*

As a result of this contract, a joint screening program will be created that builds on the scientific expertise of both partners; screening will be enhanced using advanced technology and expertise; the rate of false positive results will be reduced and consequently the medical, emotional, and financial costs to the families and the health care system will be minimized; and Minnesota will be able to rapidly expand the conditions screened when the benefits of newborn screening have been well documented. More infants will be identified with treatable disorders before the onset of the disease and the onset of irrevocable harm.

Joint Powers Agreement (Minn. Stat. §471.59, subd. 1 for Professional/Technical Services)

- 1) Explain how/why this governmental unit was selected.
- 2) Can this work be performed by any other governmental unit?

Agency Certifications. Pursuant to Minn. Stat. 16C.08, I certify:

1. *No state employee is (a) able and (b) available to perform the services called for by the contract*

A. How did you reach this conclusion:

The tandem mass spectrometry is sophisticated instrumentation whose use requires unique skill and expertise. The Mayo Clinic's Biochemical Genetics Laboratory has unique skills and expertise in the technical aspects of tandem mass spectrometry including result interpretation and confirmatory testing. Results interpretation and confirmatory testing both require a high degree of expertise and skill. Mayo Clinic's Biochemical Genetics Laboratory is the only source of this expertise in Minnesota.

B. List other methods considered for accomplishing the work. [Example: In-house, other divisions or offices, other state agencies.]

The department did consider building the capacity to do this work. However, the costs required to purchase the necessary instrumentation and to gain the needed expertise would be prohibitive.

2. *The normal competitive bidding mechanisms (low bid) will not provide for adequate performance of the service.*
3. *Reasonable efforts will be made to publicize the availability of the contract to the public.*
4. *The agency will develop and implement a written plan providing for the assignment of specific agency personnel to manage the contract, including a monitoring and liaison function, the periodic review of interim reports or other indications of past performance, and the ultimate utilization of the final product of the services. The following person has been assigned to manage the contract as well as monitor and act as liaison for the contract: Christine Everson.*
5. *No one in or on behalf of the agency will authorize the contractor to begin work before the contract is fully executed unless an exception has been granted by the Commissioner of Administration under Minn. Stat. §16C.05, subd. 2a and funds are fully encumbered.*
6. *The contract will not establish an employer-employee relationship between the state or the agency and any person performing under the contract.*
7. *In the event the results of the contract work will be carried out or continued by state employees upon completion of the contract, the agency will require the contractor to include state employees in development and training, to the extent necessary to ensure that after completion of the contract, state employees can perform any ongoing work related to the same function.*
8. *No current state employee will engage in the performance of the contract.*
9. *Reasonable efforts will be made to avoid conflicts of interest throughout the selection and performance of this contract. All potential or actual conflicts of interest will be reported to MMD.*

In accordance with Minn. Stat. §16C.08, subdivisions 2 and 3, provide the following: (attach additional pages if necessary)

- 1) Describe how the proposed contract is necessary and reasonable to advance the statutory mission of your agency;

The proposed contract is necessary and reasonable to advance the improvement of the public's health. More babies with treatable disorders will be identified and provided care prior to the onset of symptoms. The rate of false positive results will be drastically reduced, and consequently minimize the negative consequences of medical (demand of specialized services), emotional (parental anxiety and loss of productivity), and financial (costs of unnecessary care and laboratory work-up) nature.

- 2) Describe your plan to notify firms or individuals who may be available to perform the services called for in the solicitation other than advertising in the *State Register* or on the MMD website; and

We propose a sole source contract to perform these services.

- 3) Describe the performance measures or other tools that will be used to monitor and evaluate contract performance and how the results of the work will be used.

The Minnesota Department of Health will monitor and evaluate contract performance by measuring the criteria listed below.

Reduction in the rate of false positive results

Improve the analytical component of screening by tandem mass spectrometry.

Achievement of universal screening (100%) of newborns

Measures of turn around time for analysis, release of report of analysis, and laboratory follow up, clinical evaluation of abnormal cases, and treatment for babies identified as positive for a disorder.

Contract Valued Over \$50,000 (formal solicitations)

Attach both: ___ Copy of the complete Request for Proposals & ___ Proposed *State Register* Notice

Contract Valued \$5,000 to \$50,000 (informal solicitations)

- 1) Attach: ___ Informal Solicitation OR ___ Formal RFP (*Check which option will apply*)

- 2) Public Notice will be given by: (*check all that apply*)

___ Posting on the MMD Web page (Agency will post the notice). Complete the following:

Total posting time _____

Geographical location of the work _____

Agency contact person (*who vendors will contact for a copy of the informal solicitation*)

Name _____

Fax _____ E-Mail _____

___ *State Register*

___ Other as described above

Single Source Request

Identity of Contractor: Mayo Clinic's Biochemical Genetics Laboratory

Attach a justification memo. A sample can be found at www.mmd.admin.state.mn.us

The following three Internal Approval signatures are for agency use; they are not required by MMD.

Activity Manager: <i>Louise W. Hies</i>	Date: <i>July 16, 2003</i>
Division Director: <i>[Signature]</i>	Date: <i>July 16, 2003</i>
Assistant Commissioner (program): <i>Agnes T. Leitheisen</i>	Date: <i>7-18-03</i>

Agency signature (required)

Authorized Certification/Officer authorized to sign contracts: <i>Bernard Smith</i>	Date: <i>7/22/03</i>
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Minnesota Office of Technology review signature is required prior to sending the form to the Materials Management Division for requests over \$100,000 for information and communications technology activities.

Minnesota Office of Technology Reviewed (when applicable)	Date:
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Department of Administration signature (required)

Materials Management Division/Professional Technical Approval: Original signed JUL 30 2003	Date:
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July 11, 2003

By Gerald T. Joyce

Minnesota Department of Health

RETURN THIS COPY WHEN
PROCESSING CONTRACT

Memo

DATE: July 21, 2003

TO: Jerry Joyce, Department of Administration
Materials Management Division
Professional Technical Section

FROM: *Christine Everson*
Christine Everson, Assistant Division Director
Public Health Laboratory Division
717 Delaware Street SE
Minneapolis, MN 55414

PHONE: (612) 676-5384

RE: **Single Source Request**

This memo requests approval of Mayo Clinic's Biochemical Genetics Laboratory as a "single source", pursuant to Minn. Stat. §16C.10.

The technology to test newborn infant's blood to identify disorders that without treatment can cause long term disability, health problems, or even death has rapidly expanded in the past few years. The MDH evaluated a pilot program to evaluate using this new technology and determined that it is effective and efficient to expand the existing Newborn Screening program to add these new tests for all new Minnesota babies. An additional finding of this pilot project was the need to contract with an external source to work with MDH to perform the preliminary and second tier testing using specialized equipment and staff. In Minnesota, the only source of this specific service is the Mayo Clinic.

The Minnesota Department of Health proposes to contract with the Mayo Clinic's Biochemical Genetics Laboratory (BGL) to conduct advanced newborn screening using the tandem mass spectrometry instrumentation. The Mayo Clinic has extensive and unique expertise in the use of the tandem mass spectrometry instrumentation for newborn screening.

The Mayo will screen all Minnesota newborns for over thirty heritable and congenital disorders using the advanced instrumentation called tandem mass spectrometry. The efficiency and effectiveness of the newborn screening program will be increased, the rate of false positive results will be reduced, and consequently the medical, emotional, and financial costs to the families and the health care system will be minimized. More infants will be identified with treatable disorders before the onset of the disease and the onset of irrevocable harm.

(Over)

After the search described below, I have determined that the contractor is *clearly and legitimately* the single source of the proposed services for the following reasons:

The Mayo Clinic's Biochemical Genetics Laboratory is the only source of expertise in the use of tandem mass spectrometry instrumentation for newborn screening.

The Mayo Clinic's Biochemical Genetics Laboratory scientists have unique skills and expertise in the technical aspects of tandem mass spectrometry including result interpretation and confirmatory testing. Results interpretation and confirmatory testing both require a high degree of expertise and skill. Mayo Clinic's Biochemical Genetics Laboratory (BGL) is the only source of this expertise in Minnesota. In addition, Mayo Clinic possesses the specialized instrumentation necessary to perform these analyzes.

The price for this contract has been *fairly and reasonably established*, as shown by:

These funds were made available to the Minnesota Department of Health as a result of an increase in the Newborn Screening fee authorized by the 2003 legislature for the purposes described above. The level of payment for this specialized service was reviewed by the legislature as part of the fee increase to expand the program. The price per test represents a reasonable cost for the service provided.



MEMO

Date: July 21, 2003

To: Terry Smith, Accounting Operations
Financial Management

Christine Everson
From: Christine Everson, Assistant Division Director
Public Health Laboratory Division

Phone: 612-676-5384

RE: Sole Source Request Memo and PT Contract Certification Form

Please process the enclosed documents. I am enclosing the Sole Source Request Memo and two copies of the PT Contract Certification Forms between the Minnesota Department of Health/Public Health Laboratory Division and the Mayo Clinic.

Please contact me if you have any questions. Thank you for your assistance.

CE/cas
Enclosures

RECEIVED
JUL 22 2003
FINANCIAL
MANAGEMENT