

MASSACHUSETTS GENERAL PHYSICIAN'S ORGANIZATION LABORATORY SERVICES AGREEMENT

This LABORATORY SERVICES AGREEMENT ("Agreement") is dated this ____ day of _____, 20__ (the "Effective Date") by and between the Massachusetts General Physicians Organization, Inc., a not-for-profit Massachusetts corporation, having a principal place of business at 55 Fruit Street, Boston, MA 02114 ("MGPO"), acting in support of Massachusetts General Hospital's ("MGH") Department of Neurology, and _____ ("Facility") (hereinafter, the "Agreement"). The MGPO and Facility are each hereafter referred to individually as a "Party" and together as the "Parties."

BACKGROUND

- A.** The MGPO offers Neurogenetics reference laboratory services and the MGPO offers professional consulting services ("Services") on a per-request basis from similarly-situated health care facilities.
- B.** Facility owns and operates a clinical laboratory and/or private medical office practice or is an individual acting independently and, from time to time, requires Services of the type offered by the MGPO.
- C.** Facility desires to obtain Services from the MGPO, and the MGPO is willing to provide such Services to Facility, in accordance with the terms and conditions set forth herein.

NOW THEREFORE, in consideration of the foregoing and the mutual covenants, promises and agreements contained herein, the sufficiency of which is hereby acknowledged, the Parties agree as follows:

Section I – Services; Responsibilities of the Parties

1. Services. The MGPO agrees to provide Services for Facility on an as-needed basis and in accordance with all applicable federal, state and local laws, rules and regulations, as well as any applicable MGPO policies. Services shall include, but are not limited to, the following: DNA testing, biochemical testing, and DNA extraction performed on samples to provide information for the diagnosis, prevention or treatment of a disease or medical condition. All such tests shall be conducted within the timeframes set forth in Exhibit A and on a quality, professional basis consistent with applicable industry standards. The MGPO and its employees shall maintain all required licenses. The MGPO shall maintain current Clinical Laboratory Improvement Amendments (CLIA) accreditation. The MGPO will also hold accreditation from the New York State Department of Health (NYSDOH).

2. Service Orders. Every specimen must be sent to the laboratory with the appropriate test requisition form, and billing contact information. Information regarding the availability of requisition forms may be obtained by contacting the laboratory where the testing is to be performed or by visiting www.dnalab.org.

3. MGPO Responsibilities. The above Services will be made available **Monday through Friday, from 9:00 a.m. to 5:00 p.m.** to Facility. Upon completion of the Services, the MGPO will send a final report (“Report”) to Facility via facsimile. A printed copy of the report will also be sent to the Facility via U.S. Mail along with the invoice. Depending on the test, the turnaround time can range from 7 business days to 12 weeks. Please refer to our fee schedule at www.dnalab.org for estimated times.

4. Reports. The MGPO’s Report will include at least the following: patient name, date of birth, date of collection, accession number, date of report(s), name of test(s), test result(s), an interpretation of the result(s), and laboratory name and address.

5. Facility Responsibilities. Facility will deliver material to be tested (“Material”) to the MGPO’s designated receiving laboratory between the hours of 9:00 a.m. and 5:00 p.m., Monday through Friday, in a manner in compliance with the MGPO’s requirements and applicable legal requirements for such transport, as amended from time to time. As between the Parties, Facility is solely responsible for transporting Materials between the Parties and protecting against any unauthorized disclosures of protected health information while the Material is in transit (regardless of whether transfer mode is electronic or otherwise).

6. Facility’s Patient Care Responsibilities. Nothing in this Agreement shall relieve the Facility of its responsibilities for the care of its patients, including Facility’s use of test results or any other information provided to Facility by the MGPO pertaining to the Services.

Section II – Compensation & Billing

7. Fees. For Services rendered hereunder, the MGPO will bill Facility weekly, and Facility agrees to reimburse the MGPO at the rate set forth on the fee schedule found at www.dnalab.org, as the current fees to be charged to Facility for such Services. Any amendments or changes to the scheduled fees as set forth in the fee schedule shall be effective forty-five (45) days following the date upon which the MGPO has notified Facility in writing, at which time the amended fee schedule will become part of this Agreement. No tests or services will be priced or offered below the fair market value.

8. Invoicing. The MGPO’s invoices are due and payable by Facility forty-five (45) days after receipt. All payments shall be remitted to MGPO at the following address:

Massachusetts General Physicians Organization, Inc.
PO Box 3662
Boston, MA 02241-3662

9. Facility’s Billing Responsibilities. As between the Parties, Facility is solely responsible for ensuring compliance with all applicable insurance billing regulations including, but not limited to, Medicare and Medicaid reference laboratory billing regulations. The MGPO will bill Facility for Service in accordance with the fee schedule set forth in the fee schedule. It is Facility’s responsibility to bill third party payers when appropriate. If Materials are sent directly by the Facility, the MGPO will not bill the patients directly.

Section III – Confidentiality and Consent

10. Patient Information. The MGPO, all staff, employees or agents shall not disclose to any third party, except where permitted or required by law, any patient or medical record information regarding Facility's patients, and the MGPO and staff, employees and agents shall comply with all applicable federal and state laws and regulations regarding the confidentiality of such information.

11. HIPAA Requirements. To the extent applicable, the Parties agree to comply with the applicable provisions of the Administrative Simplification section of the Health Insurance Portability and Accountability Act of 1996, as codified at 42 U.S.C. § 1320d through d-8 ("HIPAA"), and the requirements of any regulations promulgated there under including without limitation the federal privacy standards as contained in 45 C.F.R. Parts 160 and 164 (the "Federal Privacy Standards"), the federal security standards as contained in 45 C.F.R. Parts 160, 162 and 164 (the "Federal Security Standards") and the federal standards for electronic transactions contained in 45 C.F.R. Parts 160 and 162, each as may be amended from time to time. The Parties agree not to use or further disclose any protected health information, as defined in 45 C.F.R. § 164.504, or individually identifiable health information as defined in 42 U.S.C. § 1320d (collectively, the "Protected Health Information"), concerning a patient other than as permitted by this Agreement and the requirements of HIPAA or regulations promulgated under HIPAA including without limitation the Federal Privacy Standards and the Federal Security Standards. The Parties shall implement appropriate safeguards to prevent the use or disclosure of a patient's Protected Health Information other than as provided for by this Agreement, or as permitted or required by law. The MGPO will promptly report to Facility any use or disclosure of a patient's Protected Health Information not provided for by this Agreement or in violation of HIPAA, the Federal Privacy Standards, or the Federal Security Standards of which that Party becomes aware.

12. Consent. Facility shall comply with all federal, state and local laws, rules and regulations related to the circumstances under which informed consent must be obtained prior to conducting genetic testing, the content of any such consent, and the manner in which genetic information may be obtained, maintained, reported and/or disclosed.

Section IV – Term and Termination

13. Term. The initial term of this Agreement shall commence on the Effective Date and terminate on December 31, 2013, unless otherwise terminated as provided herein ("Initial Term"). Thereafter, this Agreement shall automatically renew for one year periods commencing on the anniversary of the Effective Date ("Renewal Term"). Fees for Services in any Renewal Term shall be then-current rate charged by the MGPO.

14. Termination. Notwithstanding anything herein to the contrary, this Agreement may be terminated at any time as follows:

- a. By mutual agreement of the Parties; or
- b. With cause by the MGPO or Facility upon the default by the other of any term, covenant or condition of this Agreement, where such default continues for a

period of ten (10) business days after the defaulting Party receives written notice thereof from the other Party specifying the existence of the such default; or

- c. Without cause by the MGPO or Facility upon at least thirty (30) days prior written notice to the other Party in which case the Agreement shall terminate on the future date specified in such notice; or
- d. The Parties intend that this Agreement comply at all times with all applicable state, federal and local laws, including but not limited to: fraud and abuse statutes; Stark legislation; the federal Anti-Kickback Statute; laws affecting the tax-exempt status of the MGPO (e.g., IRS regulations); state MGPO licensure regulations; and federal, state and local civil rights laws; and rules and regulations of applicable healthcare accreditation organizations. In addition, throughout the term of this Agreement, each Party will ensure that its activities conducted within the context of this Agreement are in furtherance of and consistent with the MGPO's charitable missions. If, at any time, a Party in good faith determines that this Agreement does not comply with the law, or if the MGPO reasonably believes that any activities conducted pursuant to this Agreement are inconsistent with the MGPO's charitable missions, then the Parties shall use good faith efforts to conform the Agreement in such a manner so that it does appropriately comply or is consistent with such mission, as applicable. If, after the exercise of such good faith efforts, the Parties determine that this Agreement cannot be so conformed, either Party may terminate this Agreement immediately upon written notice to the other Party.

Section V – Miscellaneous

15. Use of Name. Neither Party may use the name, trademark, service mark, logo or other identifying characteristic ("Name") of the other party or any of its affiliates, or any of its or their respective directors, trustees, officers, appointees, employees, staff, representatives or agents, in any advertising, promotional or sales literature, publicity or in any document employed to obtain funds or financing without the prior written approval of the party or individual whose Name is to be used. In the case of the MGPO, such approval shall be given solely by its Director of Public Affairs. Nothing herein shall preclude a Party from disclosing the existence of this Agreement if the purpose of such disclosure is to comply with its relevant codes of conduct or ethics policies, and each Party reserves the right to publicly disclose information regarding remuneration under this Agreement, whether or not required by law, including the identity of the recipient, the source of the remuneration, the monetary value of the remuneration, and the purposes for such remuneration.

16. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts without regard to its conflicts of laws principles.

17. Entire Agreement; Written Modification. This Agreement is the entire agreement between the Parties and supersedes any other oral or written communications, proposals, quotes, advertisements or understandings regarding the subject matter hereof. This Agreement may be amended only in writing, and only if signed by both Parties.

18. Severability. If any of the provisions of this Agreement are held invalid or unenforceable, unless such invalidity or unenforceability substantially frustrates the underlying purpose and intent of the remainder of this Agreement, such invalidity or unenforceability shall not affect the remainder of this Agreement. All terms and conditions are severable and all remedies hereunder or at law or in equity are cumulative and nonexclusive.

19. Waiver. Any Party's failure to insist upon strict performance of any provision of this Agreement is not a waiver of any of its rights under this Agreement.

20. Independent Contractor. The MGPO and Facility are independent contractors for the purposes of this Agreement and neither has the authority to bind the other. No third party is a beneficiary of this Agreement.

21. Assignment; Subcontracting. The Parties may not assign or subcontract this Agreement or any of their respective rights or obligations hereunder without the prior written permission of the other Parties.

22. Interpretation. This Agreement is the product of negotiation between the Parties and shall not be interpreted for or against any Party on account of the role of a Party in the drafting hereof. Each appearance of the word "including" or "includes" shall be deemed to include the words "without limitation."

23. Survival. In addition to any specific survival references in this Agreement, any terms or obligations that by nature would be expected to survive the termination or expiration of this Agreement shall survive.

24. Counterparts; Facsimile. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which shall together constitute one and the same instrument. Signatures provided by facsimile transmission or other electronic delivery shall be deemed to be original signatures.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives as of the date first set forth above.

FACILITY:

By: _____

Name: _____
(print)

Title: _____

Date: _____

Address and Contact Information:

**MASSACHUSETTS GENERAL
PHYSICIANS ORGANIZATION, INC.**

By: _____

Name: Mario DiBenedetto

Title: Director, Budget and Financial Planning

Date: _____

Address and Contact Information:

MGH Department of Neurology

Attn: Ariel Grossman

55 Fruit Street, Wang 721D

Boston, MA 02114