MNG LABORATORIES
Neurogenetic Answers™

5424 Glenridge Drive NE
Atlanta, GA 30342 USA
toll-free: 844.TESTMNG
fax: 678.225.0212
mnglabs.com

MNG Internal Data Reassessment Form

We gladly accept deliveries Monday-Saturday, excluding holidays
CLIA License #11D0703390; CAP License #1441004; State of Georgia License #060-381

MNG Internal Data Reassessment

Standard Turnaround Time: **2-4 weeks**

Full data reassessment is available 6 months after initial report, and once per 12 month period thereafter. This service is at no cost to the patient or provider. **All data, including copy number changes and identified variants, will be re-evaluated. Variants may be identified that were not previously reported due to updated available information. An updated report will be issued with each request, whether or not any changes have been identified.**

Reassessment for all next-generation sequencing is limited to data generated at the time of initial testing. Changes and improvements to technologies may not be available for reassessment with previous versions of our assays. Updating sequencing data to the latest version or technology is available at a reduced cost. Please call for additional details.

Please complete this form in its entirety and send back to MNG via fax 678-225-0212 or email to quickresponse@mnglabs.com. For any additional reassessment inquiries, please call MNG at 678-225-0222.

Patient and Report Information	
Patient Last Name	Patient First Name
Patient ID #	Date of Birth [MM/DD/YYYY]
Gender ☐ Male ☐ Female	Date of Testing [MM/DD/YYYY]
REQUIRED INFORMATION **MNG ID# / Accession #:** _____	**REQUIRED INFORMATION** **Test Code:** _____ *Please use one form per test code*

Referring Physician Information	
Are You The Referring Physician?	☐ Yes ☐ No (if no, please include medical record release)
Referring Physician Name	Signature
Referring Physician **NPI # [Required]** or international equivalent	
Facility / Organization	Phone
Select and Provide Email or Fax for Report Delivery	☐ Email ☐ Fax

Results (sent by secure HIPAA-compliant email or fax)	
Authorized Recipient Name	Authorized Recipient Name
Facility	Facility
Phone	Phone
☐ Fax ☐ Email	☐ Fax ☐ Email

Any additional or updated clinical information for the proband is encouraged. Please include any additional family testing that has been performed if outside of MNG, or clinical details regarding newly affected family members.

MNG LABORATORIES
Neurogenetic Answers™

5424 Glenridge Drive NE
Atlanta, GA 30342 USA
toll-free: 678.225.0222
fax: 678.225.0212
mnglabs.com

Informed Consent: Data Reassessment

We gladly accept deliveries Monday-Saturday, excluding holidays
CLIA License #11D0703390; CAP License #1441004; State of Georgia License #060-381

Notice to Health Care Practitioner:

This document is a consent form for Data Reassessment. Currently, the laboratory will only accept Data Reassessment requests after the patient/parent or legal guardian/next of kin has approved of having their data reassessed and this form accompanies the test request form. Please be aware of any applicable state laws in regards to counseling needs related to the current condition, the possibilities of detecting unsuspected conditions as well as other issues related to health insurance, and possible effects on life insurance. Please explain this consent to the patient, or authorized representative/ guardian, and obtain an informed consent. Please explain the list of potential incidental findings that may be reported to the patient.

Informed Consent for Patients and/or Legal Guardians:

Why is my genetic data being reassessed?

Your practitioner believes that having your genetic data reassessed by another laboratory skilled at Data Reassessment may offer additional valuable information as to the diagnosis of diseases(s) Because reassessment results have potential consequences for your family members, we recommend that the consenting and ordering process be performed with the assistance of a genetic counselor and/or the ordering physician.

What kind of results are reported?

1. Positive: Mutation(s) have been identified that are known to cause the disease symptoms based on the available scientific evidence at the time of testing.
2. Indeterminate: Mutation(s) have been identified that are likely to cause the disease symptoms based on the available scientific evidence at the time of testing, but there is a lack of definitive scientific evidence available to prove it.
3. Negative: No mutation has been identified that is known or likely to cause the disease symptoms based on the available scientific evidence at the time of testing.

What implications do positive and negative results have?

When a Data Reassessment detects known disease causing mutations, the analysis is highly accurate. A positive result will help your clinician to better predict the course of the condition and provide you with treatment options, if they exist. The results will also help determine the risk of recurrence of the condition in other children. An indeterminate result will point to a probable cause of a condition, but you may wish to consult a genetic counselor or your physician and undergo further independent testing to confirm or rule out the proposed role. A negative result does not indicate the absence of a genetic cause and will not change the clinical diagnosis.

Are there limitations to the reassessment of genetic data?

There is a possibility a pathogenic variant will be missed by the review either because of the technical limitations of the data provided, or because of incomplete understanding of the significance of the variants detected.

What are incidental findings?

During testing, disease causing mutations can be identified that are not related to the patient's condition for which the testing was done. These are referred to as "Incidental Findings" and indicate the presence of previously undiagnosed, potentially serious conditions that can be prevented or treated if diagnosed. A list of such conditions based on the recommendation of the American College of Medical Genetics (ACMG) is provided on our website. Please state whether you want to be informed about incidental findings in relation to the conditions listed.

_____ (initials) I would like to learn of incidental findings to the conditions listed.

_____ (initials) I would NOT like to learn of incidental findings to the conditions listed.

MNG LABORATORIES
Neurogenetic Answers™

5424 Glenridge Drive NE
Atlanta, GA 30342 USA
toll-free: 678.225.0222
fax: 678.225.0212
mnglabs.com

We gladly accept deliveries Monday-Saturday, excluding holidays
CLIA License #11D0703390; CAP License #1441004; State of Georgia License #060-381

Are there results that will not be reported?

1. Samples from the patient's relatives may be used to help diagnose the patient's condition, but results for these relatives will not be reported. However, the patient's genetic results may have implications for their relatives. Therefore, it is important that these implications are discussed with a genetic counselor.
2. Variations in genes that affect susceptibility to a condition, but do not cause the person to develop the condition will not be reported.
3. Carrier status for recessive disorders will not be reported: Most people carry mutations that are not disease causing but could become disease causing if that person had children with someone who was healthy, but had the same mutation. This is referred to as being a "carrier" for a disease. If you are concerned about carrier status for conditions that might run in your family, you should get tested separately for carrier status. You should discuss these implications with your genetic counselor.

Who will have access to the results?

Test results are maintained electronically by the laboratory. The results are provided to the ordering physician and/or health care facility that ordered the reassessment. Results may also be made available to individuals/organizations with a legal right of access under applicable Federal and/or State law, or as authorized by the patient or the patient's representative. Patient privacy is of utmost concern to us, and we adhere to HIPAA privacy and security requirements.

How long are data reassessment results kept in the lab?

The laboratory may keep the submitted raw data in the lab indefinitely. This helps us improve our diagnostic capabilities and will help others with similar conditions. To advance the understanding of genetic disorders, your results may be analyzed and published in scientific articles in a de-identified manner consistent with HIPAA guidelines.

_____ (initials) We agree that our data may be stored indefinitely.
_____ (initials) We agree that our data may be used for scientific publication in a de-identified manner.

What are the risks of Data Reassessment testing?

1. Non-paternity (when the reported father of the child is not the biological father) or half sibling-ships (when siblings do not share the same father AND mother) would be detected. We do not report these findings unless they have direct clinical significance.
2. Genetic non-discrimination law prevents insurance companies from using your genetic information to deny health insurance coverage, but the law does not cover life insurance, disability insurance or long term care insurance. The detection of an incidental condition may affect your future ability to buy these forms of insurance or get the best insurance rates. Please be aware of any applicable State laws and applicable terms of any active insurance policies in regards to consent and the release of these results to insurance companies.
3. Data Reassessment may identify serious and/or untreatable genetic conditions. It can result in unexpected psychological trauma, both for you and your family. The detection of such a condition or conditions could also affect the health or health care needs of your siblings, children, or other close relatives.
4. Although Data Reassessment is highly accurate, the interpretation of the report is based on current medical knowledge.

MNG LABORATORIES
Neurogenetic Answers™

5424 Glenridge Drive NE
Atlanta, GA 30342 USA
toll-free: 678.225.0222
fax: 678.225.0212
mnglabs.com

We gladly accept deliveries Monday-Saturday, excluding holidays
CLIA License #11D0703390; CAP License #1441004; State of Georgia License #060-381

Consent for Data Reassessment Testing

All of the above has been explained to me, to my satisfaction, and my signature below attests to the same. I understand that this is a voluntary test, and I have had the opportunity to ask questions about alternative testing.

Data Reassessment Participant (Parent/Guardian of child being tested):

Print Name: _____ Date: _____

Signature: _____ Date of Birth: _____

I have provided genetic counseling and have explained the risks, benefits, and limitations of Data Reassessment testing to the patient/parent/guardian.

Health Care Provider Obtaining Consent:

Print Name: _____ Date: _____

Signature: _____ NHI#: _____

Consent of family members submitting a sample for evaluation of patient's results.

I understand that I am submitting my blood sample to help evaluate the results obtained on the person being tested, and that results obtained from my sample will be used solely for this purpose. I will NOT be informed of any test results on my sample. If I request any test results, I will have to be tested separately. If questioned by an insurance carrier, I can state that I have not been tested personally for any conditions.

Name of Family Member: _____ Relationship to Person: _____

Signature: _____ Date: _____

Name of Family Member: _____ Relationship to Person: _____

Signature: _____ Date: _____

Name of Family Member: _____ Relationship to Person: _____

Signature: _____ Date: _____