Note to the Ordering Health Care Provider: Some states require that patients (or their authorized representatives) provide informed consent prior to receiving genetic testing, and that the ordering healthcare provider maintain the documentation of the informed consent in the patient's medical record. This form is intended to assist health care providers located in New York with obtaining the patient's informed consent in accordance with applicable law.

Informed Consent for Genetic Testing

Patient Name:_____ Patient ID number:_____

Patient Date of Birth:_____ Ordering Provider Name:_____

General description and purpose
My health care provider has discussed the following test(s) with me:_____

_____

My health care provider has explained that the purpose of the test(s) is to look for variants or other genetic alterations that can be associated with the following disease(s) or condition(s):_____

_____

My health care provider has provided me with information about the test(s) to be ordered and has explained the possible risks and benefits of testing.

Purpose and Implications of Genetic Testing
Genetic testing is a type of laboratory test that provides information about genes, chromosomes, or proteins using samples of blood, saliva, or other tissue. Genetic tests identify similarities or modifications in your genetics against known genetic information of a larger population and could indicate genetic tendencies for the tested genetic condition or your status as a carrier.

You may wish to obtain professional genetic counseling prior to signing this consent form.

Possible Results and Significance of the Results
The results of the genetic test could be:

- Positive. A positive result may confirm you are a carrier of a particular gene or at increased genetic risk for developing a genetic-linked condition. Further evaluation, and possible testing, with your health care provider should be sought to develop any diagnosis. The ability of genetic testing to provide risk information or level of certainty varies with the type of test. A positive test result may help you and your health care provider make a plan to reduce the chance of developing a particular health condition in the future.

- Negative. A negative result means that the clinically significant variant tested was not detected. A negative result does not: (i) guarantee that you will not develop a disease or condition, (ii) eliminate the need for additional genetic testing, (iii) rule out having a DNA variant in the genes tested, or (iv) rule out having hereditary conditions linked to the genes included in the test.

- Of uncertain significance. A result of uncertain significance may (i) lead to a suggestion that additional testing may be helpful, (ii) remain uncertain for the foreseeable future, or (iii) be resolved over time.

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Limitations and Effectiveness of Genetic Testing
There are several limitations of genetic testing, including:

- Genetic testing analyzes specific gene regions related to the topic of the testing. It does not look for or test for all genetic conditions, and does not rule out the possibility of an undetected variant in other gene regions.
- In some cases, genetic testing may indicate an abnormality in a gene, but no genetic disorder may manifest.
- Genetic testing may indicate a genetic abnormality when the individual is actually unaffected (false positive) or may indicate no genetic abnormality when the individual is actually affected (false negative).
- There may be new discoveries in the future about genetic testing that impact the results, as what is known today about the test and results may change over time.
- There may be possible sources of error including, but not limited to, trace contamination, donor DNA from transplants or transfusions, rare technical errors in the laboratory, rare DNA variants that compromise data analysis, inconsistent scientific classification systems, and inaccurate reporting of family relationships or clinical diagnosis information.

Performance of the Genetic Testing and Disclosure of Results
The genetic testing described above will be performed on the sample collected by your health care provider or Quest Diagnostics. The health care provider who ordered your test will receive the test report and will share the results with you. If you use the MyQuest® portal, the test results will also be available in the portal. Quest Diagnostics will follow your health care provider's instructions and all applicable laws when providing your test results in the MyQuest® portal.

You have a right to confidential treatment of your laboratory records and results. Unless you provide additional written consent, or unless required by law, Quest Diagnostics will not share your test results with anyone except your health care provider and health insurer. Quest Diagnostics may use your results and/or specimen in connection with operational activities such as quality control and assurance, validation of test performance and product development and improvement, as permitted by applicable law. Quest Diagnostics may share de-identified variant data with ClinVar, a public archive of genetic variants that diagnostics laboratories contribute to. Variant information shared with ClinVar contains no personal identifiers that can be linked back to you.

Your sample will be destroyed or anonymized after the end of the testing process, or not more than 60 days after the specimen was taken. Anonymizing your sample permanently removes any data that could identify you. Quest may perform genetic tests on anonymized samples for research or statistical purposes. Unless your sample is anonymized, no additional testing will be performed on your sample.

Patient Authorization (REQUIRED):
My signature below indicates that I have received information about this test in order to provide informed consent. I have been given a full opportunity to ask questions that I may have about the testing procedure and related issues.

By signing this consent form, I give consent to my health care provider and Quest Diagnostics to order the genetic test, collect my sample and perform the genetic test. I consent to the collection, use, disclosure, retention and other processing of my data and sample as described above.

_____		_____
Signature of Patient		Date
_____	_____	_____
Signature of Patient Representative	Relationship	Date

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For the Doctor/health care provider (REQUIRED):
As the referring doctor/health care provider I understand the benefits and limitations of the genetic test(s) ordered and have requested that the patient listed above be tested. I attest that I have provided the patient and the patient's representative with the information contained above and fully answered any questions. I believe that the patient and the patient's representative understand(s) the information and is/are voluntarily signing this informed consent.

_____ _____

Signature of Doctor/Health care provider/ Date

_____

Print Name of Individual Obtaining Consent

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