

Informed Consent for Genetic Testing

Patient Name: _____ Date of Birth: _____

Name of Test: _____ Sex: M / F / Other

Your provider has ordered the genetic test(s) listed above. A detailed description of the disease condition, the genetic test, and what it is used for is available at MachaonDiagnostics.com. You may also ask your provider to explain what this test is and why they have ordered it.

We encourage you to seek physician or professional genetic counseling prior to giving consent and for review of your genetic results.

- It is important that you provide accurate information about symptoms and family history to enable correct test selection and interpretation. In cases where a family member has tested positive for a genetic abnormality (variant), a copy of that report may be required by the laboratory before testing can be started.
- Results from genetic testing may be positive, negative or equivocal (inconclusive).
 - A positive result may confirm whether a person is affected with, a carrier of, or at risk for developing a genetic condition.
 - A negative result does not exclude the possibility of being affected with or a carrier of a genetic condition. Genetic conditions may have many causes, some of which may not be completely known or testable.
 - An inconclusive result (referred to as an “equivocal” result) may occur due to limitations of laboratory methods, limitations in knowledge of the clinical significance of identified variant(s), or poor sample quality.
- Identified genetic variants are interpreted using current information in the medical literature and scientific databases. This information may change, and Machaon may issue a revised report if the clinical significance of the variant changes. Individuals should consult their healthcare provider at least annually to determine if new information is available about their result.
- Genetic testing results may provide information that was not anticipated, such as:
 - Identifying a genetic risk unrelated to the original reason for testing.
 - Predicting another family member has, is at risk of, or is a carrier of a genetic condition.
 - Revealing non-paternity (the person stated to be the biological father is not, in fact, the biological father).
 - Suggesting the parents of the individual tested are blood relatives.

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- Although genetic test results are usually very accurate, several sources of error are possible, including clinical misdiagnosis of a condition, inaccurate information provided regarding family relationships, sample mislabeling or contamination, recent transfusion, bone marrow transplantation and maternal cell contamination of prenatal or cord blood samples.
- If a genetic variant is identified, insurance rates, the ability to obtain disability and life insurance, and employability could be affected. The Genetic Information Nondiscrimination Act of 2008 extends some protections against genetic discrimination. Results are released to the ordering health care provider or referring lab and parties entitled to them by state and local laws.
- Because Machaon Diagnostics is not a storage facility, most samples are discarded after testing. Some samples may be stored indefinitely for test validation or education purposes after personal identifiers are removed. All New York samples are discarded 60 days following test completion. You may request disposal of your sample by calling Machaon Diagnostics at (800) 566-3462.
- Machaon Diagnostics may submit HIPAA-compliant, de-identified (cannot be traced back to the patient) genetic test results and health information to public and private databases. The confidentiality of each sample is maintained. If you prefer that your test result not be shared, please call Machaon at (800) 566-3462.

Patient/Legal Guardian: My signature below constitutes my desire to undergo genetic testing through Machaon Diagnostics and my acknowledgment that the benefits, risks, and limitations of this testing have been explained to my satisfaction by a qualified health professional.

Printed Name

Signature

Date

Ordering Healthcare Provider: I have explained the listed genetic test, its limitations and alternatives to the patient or legal guardian and I have answered all questions to the best of my ability.

Printed Name

Signature

Date

