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GENETICS INFORMED CONSENT FORM

THE PURPOSE OF GENETIC TESTING

My healthcare provider has recommended that I receive genetic testing and has explained the purpose of the tests to me. A genetic test is performed by a clinical laboratory that identifies a person's unique genetic makeup by analyzing a person's DNA, RNA or proteins using specialized reagents and instruments. Depending on the specific type of genetic test ordered, a person's genes may have variants, many of which can be analyzed and interpreted for known genetic conditions. A genetic test can:

- Confirm a diagnosis that is already suspected based on family history or a medical examination (diagnostic test)
- Determine the possibility of developing a disease or condition in the future (predictive or pre-symptomatic test) and/or
- Determine whether a genetic carrier state exists (carrier test)

The effectiveness of genetic testing depends on multiple factors including ordering the right type of genetic test.

WHAT FORMS OF TEST OUTCOMES MIGHT I ANTICIPATE FROM GENETIC TESTING?

1. **Positive:** Your DNA has undergone a change, which is almost certainly causing your characteristics and symptoms. This is the most apparent test result, and it can be useful to act as the starting point for testing family relatives to discover their likelihood of developing the said condition. It should be realized that there are possible sources of error due to trace contamination, rare technical errors, rare genetic variants that interfere with analysis, recent scientific developments and alternative classification systems.
2. **Negative:** There were no modifications in your DNA that could account for your symptoms. This does not imply that you are free from a hereditary disorder. Following up with your healthcare provider is needed.
3. **Variant of Uncertain Significance (VUS):** A gene alteration was identified, but it cannot be determined if this variation is causing your symptoms. Testing of additional family members may be recommended to confirm the results. Following up with your healthcare provider is needed.
4. **Unexpected Results:** In a small percentage of cases, this exam may identify a significant gene mutation that is unrelated to the original intent for ordering it. It may reveal that you are at risk for another genetic disorder not connected to the original inquired disorder. Following up with your healthcare provider is needed.

RISKS, RESTRICTIONS AND CHALLENGES OF GENETIC TESTING

1. Physical risks of genetic testing are small. The risk associated with having a blood sample drawn will be explained before collecting the sample.
2. Psychological and social risks related to genetic test results may affect a person or family's emotions. A genetic counselor may be sought out prior to getting the genetic test. All results should be discussed with your health provider. For some insurances, genetic counseling before testing is required.
3. Testing may fail to detect a genetic condition that is present. This could be a result of technological or medical knowledge constraints. Certain types of variants may not be detected. Additionally, it may not be possible to fully resolve certain details about your variants. The report reflects the analysis of an extracted genomic DNA sample. While this test is intended to reflect the analysis of extracted genomic DNA from a referred patient, in very rare cases the analyzed DNA may not represent that individual's constitutional genome, such as in the case of a circulating hematolymphoid neoplasm, bone marrow transplant, blood transfusion, chimerism, culture artifact or maternal cell contamination.
4. Establishing a family's underlying biological links may be necessary for the best analysis of findings. I am aware that if I don't adequately describe the biological connections in my family, the findings might be misinterpreted, or an incorrect diagnosis may be made. Additionally, I understand reports may reveal unexpected relations such as non-paternity (the reported father is not the biological father) and consanguinity (the parents are blood relatives).
5. Despite the high accuracy of genetic testing, false positives can nevertheless occur. False positives may arise from mislabeled samples, erroneous reporting of clinical data, uncommon technical failures, and/or various other factors.
6. I am aware that this test might not catch all of the long-term health issues I might encounter and my condition may require further testing.

7. If the first sample is insufficient, I agree to provide another one.
8. I agree to let the lab know if I am already aware of the specific gene mutation(s) or chromosomal rearrangement(s) that cause the genetic condition(s) in my family.

PATIENT CONFIDENTIALITY

To protect patient privacy, results will only be disclosed to the ordering healthcare provider and other healthcare providers involved in my care, diagnosis, and treatment. Unauthorized disclosure of this knowledge is prohibited by federal law.

SAMPLE HANDLING AND RETENTION

Genetic tests are always handled following a practical chain of custody process and in a confidential manner adhering to HIPAA, State, and Federal law. Unless you or your healthcare provider inform Virant Diagnostics otherwise, my sample will not be used in any identifiable fashion for research purposes without my consent.

CONSENT TO OBTAIN A SPECIMEN FOR GENETIC TESTING

1. I have been informed about the nature, voluntary aspect, and purpose of this genetic test.
2. I have received an explanation of the effectiveness and limitations of this genetic test.
3. I have discussed the benefits and risks of this genetic test with my physician and/or other healthcare provider. I understand some genetic tests can involve possible medical, psychological, and/or financial challenges. I have the option of obtaining professional genetic counseling prior to signing this consent.
4. I understand the meaning of possible test results and have been informed how I will receive the result. No other tests other than those authorized shall be performed on the biological sample taken from me.
5. I have been informed that genetic testing can sometimes reveal incidental or secondary findings that are not related to the purpose of testing. I have discussed with my healthcare provider if and/or how such results will be shared with me. I understand that I can decide whether I want secondary results reported back to me and what secondary results I want to be reported.
6. I have been informed who may have access to my biological sample and that any leftover sample may be retained by the laboratory.
7. I have been informed who may have access to my genetic test result, which is part of my confidential medical record.
8. I am mindful that Virant Diagnostics may use family relatives' sample(s) when analyzing my findings and that my report may disclose clinical and genetic information on family relatives to help interpret the test results. I am also aware that family relatives will not receive a separate review of the data.
9. Financial responsibilities:
 - a. I acknowledge that Virant Diagnostics will bill my insurance company on my behalf and will release any information necessary for payment. I hereby fully assign Virant Diagnostics and request that payment be delivered to them directly.
 - b. I am aware that, depending on the results of a benefit inquiry, my out-of-pocket expenses might differ from the anticipated balance(s) that Virant Diagnostics has provided to me. I accept financial responsibility for any balance(s) stated in the health insurance plan's description of benefits. I agree to endorse the insurance check and deliver it to Virant Diagnostics as payment toward Virant Diagnostics' services.
 - c. If I do not possess health insurance, I agree to pay the expense of the genetic testing that was requested by my healthcare provider and billed to me by Virant Diagnostics. I accept the financial responsibility for genetic testing ordered by my healthcare provider as proven by signing Patient Consent/Authorization on the Virant Diagnostics Genetics Test Requisition Form/Angioedema Complement Assays and Genetics Test Requisition Form or the bottom of this form.
10. My questions have been answered to my satisfaction.

I consent to have a sample processed for genetic testing at Virant Diagnostics:

Signature

Printed Name

Date

Relationship to patient: Self Parent Legal Guardian Durable Power of Attorney for Health Care

Name of patient if not same as above:

Patient Last Name

Patient First Name

Patient Date of Birth

For family relative(s) providing sample(s) for Carrier Testing or Whole Exome Sequencing:

Family Relative 1 Signature

Family Relative 1 Printed Name

Date

Family Relative 1 Relationship to Patient

Family Relative 2 Signature

Family Relative 2 Printed Name

Date

Family Relative 2 Relationship to Patient