

Informed Consent – Virant Diagnostics, Inc.

THE PURPOSE OF GENETIC TESTING

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 called mutations, 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), determining the possibility of developing a disease or condition in the future (predictive or pre-symptomatic test) or determining whether a genetic carrier state or birth defect 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 extended family members to discover their likelihood of developing the said condition.
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. It's likely that more testing may be suggested by your healthcare provider.
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.
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.

RISKS, RESTRICTIONS AND CHALLENGES OF GENETIC TESTING

1. Physical risks of genetic testing is small and associated with having a blood sample is drawn, which will be explained before getting the sample.
2. Psychological and social risks related to how the genetic test results may affect a person or family's emotional or intellectual reactions. A genetic test result may create unexpected relationships. A genetic counselor may be sought out prior to getting the genetic test.
3. Testing may fail to detect a genetic condition that is present. This could be a result of technological or medical knowledge constraints.
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 agree with reports and relations including 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 various other factors.
6. I am aware that this test might not catch all of the long-term health issues I might encounter and may require further testing.
7. If the first sample is insufficient, I agree to offer another one.
8. I agree to let the lab know if I am already aware of the specific gene mutations or chromosomal rearrangements that result in the genetic condition 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 handled in a confidential manner. For sample retention, please choose one:

- The biological sample taken from you will be destroyed at the end of the testing process, or not more than sixty (60) days after the sample has been taken.
- You are authorizing the lab to retain your collected sample for future directed analysis by you or your healthcare provider, or for use by the lab for research use only.

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 professional. I understand some genetic tests can involve possible medical, psychological or insurance issues for my family and me. 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- results that are not related to the purpose of testing. I have discussed with my healthcare professional if and/or how such results will be shared with me. I understand that it is up to me to 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 the relative sample(s) when analyzing my findings, and that my report may disclose clinical and genetic information on a relative so it will help interpret the test results. I am also aware that relatives won't get a separate review of the data.
9. Financial responsibilities:
 - 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 to Virant Diagnostics and request that payment be delivered to them directly.
 - I am aware that, depending on the results of a benefit inquiry, my out-of-pocket expenses might differ from the anticipated sum that Virant Diagnostics has provided to me. I accept financial responsibility for any sums 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 Diagnostic's services.
 - If I do not possess health insurance, I agree to pay the expense of the genetic testing that was requested by my healthcare professional and billed to me by Virant Diagnostics. I accept the financial responsibility for genetic testing ordered by my healthcare practitioner as proven by signing the Virant Diagnostics Test Requisition Form or the bottom of this form.
10. My questions have been answered to my satisfaction.

I consent to have a sample taken for genetic testing at Virant Diagnostics on the named person :

Signature: _____ Printed Name: _____ Date: _____
 Check one: Self Parent(s) Legal Guardian Durable Power of Attorney for Health Care