

Informed Consent

For children who cannot consent for ordered testing themselves, "I", "my", and "your" will refer to me or to my child.

OBJECTIVE OF THIS TEST

This test is to examine whether I might have a gene mutation or chromosome rearrangement that produces a genetic condition. It is also intended to determine the likelihood that I will eventually develop or transmit a genetic disorder. 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.

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.

WHAT IS TRIO/DUO-BASED GENETIC TESTING?

For some genetic tests, it may be helpful to consider the genes of a patient's biological parents or other biological relatives in the assessment of the findings. Since they typically involve samples from the patient's parents as well, these tests are referred to as "trio tests." Relative samples should be provided along with the patient's samples.

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.

RESTRICTIONS AND CHALLENGES OF GENETIC TESTING

1. Testing may fail to detect a genetic condition that is present. This could be a result of technological or medical knowledge constraints.
2. 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).
3. 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.
4. I am aware that this test might not catch all of the long-term health issues I might encounter and may require further testing.
5. If the first sample is insufficient, I agree to offer another one.

PATIENT CONFIDENTIALITY

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

SAMPLE RETENTION

If no specific prior arrangements have been made, Virant Diagnostics will not deliver DNA samples to you or to healthcare practitioners.

FINANCIAL RESPONSIBILITY

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.