

PATIENT INFORMED CONSENT FOR GENTIC TESTING



*REQUIRED

Name of person being tested*: _____

Date of Birth of person being tested*: _____

Gender of person being tested*: _____

I understand that I/my child am/is submitting a sample for the purpose of identifying DNA variants to Avantra Genetics ("Avantra") as ordered by my physician. I have discussed the benefits, risks, and limitations of this testing with my healthcare provider, and have had my questions answered. By signing below, I give consent to have my/my child's DNA sample sent to Avantra for testing.

SIGNATURE

My signature below acknowledges that I give my consent for genetic testing and I understand the medical and financial outcomes, including the benefits, risks, and limitations, as described above.

Patient signature or parent/guardian (Print and sign)*

Email

Patient phone number

Address

City/State/ZIP

Date of collection

Physician name

ABOUT AVANTRA'S NEXT-GENERATION SEQUENCING GENETIC TEST

Next-Generation Sequencing (NGS) is a method of detecting changes in an individual's DNA sequence. These changes or "variants" represent differences in a person's DNA as compared to the DNA of a large number of asymptomatic individuals. Avantra will use NGS technology to identify rare or common single nucleotide variations (SNVs) and common single nucleotide polymorphisms (SNPs). Variants will only be identified in genes that have been listed as being evaluated by this test. Variants detected by NGS will not be confirmed using a second method of genetic testing, such as Sanger sequencing.

The SNVs and SNPs identified by this test will not be reviewed or interpreted by laboratory geneticists. The results are intended for informational use only and are meant to be evaluated by a healthcare provider. Though the genetic information included in this report may be used to gain insight into how your genes may contribute to your symptoms, all medical management decisions are at the discretion of the treating healthcare provider.

Although this test may identify rare variants in your DNA that are diagnostic for a single gene disorder, it is not meant to evaluate for monogenic causes of disease (where one known genetic change leads to all symptoms). There are other types of genetic tests available that can identify single gene disorders, and your healthcare provider may recommend other genetic or laboratory tests in conjunction with Avantra's NGS test.

POTENTIAL TEST RESULTS

Avantra's test reports will include:

- Variants observed in the DNA sample, with a description of the variant (e.g. change to DNA sequence, predicted change to gene product, frequency of the variant in healthy people), and other information that may be used by your provider to determine the significance of the variant.
- Descriptions of each gene in which a rare variant was found, with links to resources, and
- The presence or absence of selected single nucleotide polymorphisms (SNPs).

TEST LIMITATIONS AND CONSIDERATIONS

This test will provide a list of rare and common SNVs, as well as SNPs found in the DNA sample provided. It will not have a clinical interpretation of these variants or SNPs. This means that Avantra will not compare your genetic test results with your symptoms to determine which variants may be related to

Where to send completed forms:

If you have received this form with your sample collection kit, you MUST return this form with your sample in the box provided. A photocopy of the signed form is acceptable.

Via secure fax: 617-892-7192

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disease. The ordering physician is responsible for interpreting this test and making recommendations to you based on the results. If you have questions regarding your test results, you should contact your physician or other health-care provider.

Avantra will not provide you with an interpretation or a “score” for any variant identified your DNA. This means that you may have a pathogenic (disease-causing) variant identified by this test that will not be reported to you as disease-causing.

Avantra will not utilize a second method of genetic testing, such as Sanger sequencing, to confirm the presence of any variants in your DNA. This means that your report may contain variants that appear to be present based on the Next-Generation Sequencing technology, but are not true changes in your DNA (“artifact”). For every 100 variants identified by this test, about 1 will be an artifact of NGS.

Genetic testing for your family members will not be performed as part of this test. Other types of genetic testing may include the option of “familial testing,” which can help to interpret variants that are found in your DNA. Since Avantra does not provide any interpretation of your test results, we will not accept or process samples for confirmatory testing for any family members.

GENETIC COUNSELING

Genetic counseling is the process of providing individuals and families with information on the nature, inheritance, and implications of genetic disorders to help them make informed medical and personal decisions. Avantra is available to offer suggestions for such providers in your area should you wish to see one. Avantra does not provide genetic counseling services.

RISKS OF DISCRIMINATION

The Genetic Information Nondiscrimination Act (GINA) of 2008 prohibits health insurance plans and employers from discrimination based on genetic information, including the results of genetic testing. However, such genetic testing may result in life insurance, disability insurance and/or long-term care insurance discrimination that is not prohibited by law.

DNA SAMPLE AND RESULTS DISCLOSURE

I authorize Avantra to release the test results to the ordering physician and any other health care provider that I designate in writing. Test results may be released to any entity that, by statute of law, has the legal authority to request and receive genetic test results.

I understand that DNA samples will be used for testing that is authorized by an ordering physician and any subsequent related or follow-up testing ordered by the physician. Any leftover sample of genomic DNA will stored for two (2) years at which point it will be discarded. Samples from New York residents will be discarded 60 days after testing unless the individual opts in by signing below. Some samples may be maintained indefinitely after all testing has been completed for use in clinical tests and/or for research purposes to advance scientific knowledge. In such a case, all personal identifiers will first be removed, and I will not be informed of any results, as Avantra will have no means to determine the sample origin. In addition, I understand that Avantra may discuss summaries of genetic test results in scientific presentations, publications, or marketing pieces given that no names or personal identifiers are revealed. Unless opted in below, residents of the state of New York will be excluded from sample retention beyond 60 days and from allowing Avantra to use their genomic data for research purposes.

OPT-IN REQUIRED FOR NY RESIDENTS (SIGN HERE)
