

myGenome INFORMED CONSENT FOR GENETIC TESTING

I understand that:

1. Voluntary Participation. This form describes the benefits, risks, and limitations of screening my genome. I acknowledge that my participation in genetic screening is voluntary.

2. Test Purpose. I acknowledge that Veritas Genetics will be performing whole genome sequencing (WGS) analysis and interpretation on my genetic material (termed DNA). This test will sequence or “read” all of my DNA, and variations (“misspellings”) in my genetic material will be identified. WGS analysis seeks to make correlations between DNA variants in an individual’s unique genome and the presence of or risk for a variety of diseases and traits. I acknowledge the potential use of my WGS data and interpretation in my health care as discussed below.

I understand that this is a screening test for healthy individuals. It is not a diagnostic test. It should not be used to diagnose a known or suspected disease in myself or my family. If I have concerns about a disease in myself and/or my family, I am aware that I should discuss appropriate medical and/or genetic testing options with my healthcare provider.

3. Background Information. I understand the following background information on WGS:

a. Every individual is made up of trillions of cells. Cells can be thought of as small, microscopic packets containing our DNA. DNA is stored in the form of a 4 letter alphabet (A, C, T, and G).

b. DNA is necessary for the normal health and maintenance of our body. It is particularly important because it allows one’s genetic information, which influences health and physical characteristics, to be passed down from one generation to the next. Each parent contributes 50% of their DNA to their children.

c. Genes are segments of coding and non-coding DNA that provide instructions for the formation of proteins and other important biological compounds. Changes found in an individual’s genes or DNA can cause disease or increase one’s risk for disease. Conversely, gene changes may also be protective against certain illnesses and diseases.

d. Each individual has over 40,000 genes. Over 3,500 of our genes have well-established associations with a variety of illnesses and diseases.

e. A genome is the complete set of one’s genetic material. It is comprised of both coding and non-coding portions of DNA. Variations can occur in the coding and/or non-coding DNA. These variations may positively or negatively contribute to one’s health.

WGS looks at both the coding and the non-coding regions of our DNA, as opposed to Whole Exome Sequencing (WES) which only looks at the coding regions (exons) and represents approximately 1-2% of the entire genome. Analyzing the entire genome can provide predictive health information on an individual’s and their family’s risk for various illnesses and diseases.

4. Screening of Myself, not children. I affirm that I am at least 18 years old and am the person ordering this screening test. I agree that Veritas Genetics can release to legal authorities as it deems appropriate any of the information provided if they determine the preceding sentence may not be accurate. Special arrangements must be made for screening of any individual who is a minor or is deceased.

5. Reporting.

a. I understand that my genomic data will be analyzed and a written report will be provided to me and my ordering physician to download via my access to the Veritas Genetics online web portal. Additionally, my results will be available to view on Veritas’ myGenome interactive application; access to this application will also be available via the web portal.

b. The report will provide interpretation on approximately 2000 genes as determined by Veritas Genetics. A complete list of current gene offerings can be found on the website (www.veritasgene.com). These genes are associated with specific genetic syndromes in various organ systems (i.e. ACMG 56, see below), drug metabolism, physical characteristics/appearance, and ancestry.

In 2013, the ACMG (American College of Medical Genetics) published recommendations for the return of results revealing “pathogenic variants” (variants known and/or highly suspected to be disease causing) in 56 genes across 24 disorders (spanning inherited cancers, cardiomyopathies, cardiac arrhythmias, and connective tissue disorders) in any individual (adult and child) undergoing clinical genome sequencing. This screening includes checking the most supported public databases (e.g. ClinVar) for the presence of variants in these ACMG recommended genes.

c. Genomic variants expected to be predictive of disease or carrier status identified in my genome will be reported. Only those variants classified as pathogenic or likely pathogenic in the private and public databases utilized by Veritas Genetics will be reported on. (Excludes variants pertaining to traits, ancestry and protective alterations). However, I acknowledge that there may be clinically relevant variants present in my genome that are not reported on. This is due to the possibility that variants in such databases may unknowingly be misclassified (i.e. a pathogenic variant is inaccurately classified as benign or a benign variant is inaccurately classified as pathogenic). Furthermore, a variant that is reported as pathogenic in the medical literature, may not be included in the largest or most used public databases resulting in the absence of this variant in my report.

d. A supplemental report including all variants of uncertain significance (VUSs) will also be provided. Please see below for an explanation of VUSs.

e. I understand that my raw data will not be provided. However, a Variant Call File (VCF) is available upon request and may incur additional fees. This file will include all types of variants (benign, inconclusive (VUS), pathogenic, etc.) identified in my genome. I understand these variants will be limited to previously reported variants in the private and public databases utilized by Veritas Genetics. Therefore, the VCF may not be inclusive of every coding/non-coding region of my genome. I understand that my results and any sequencing data are provided only for my non-commercial, personal use.

6. Types of Results.

a. Pathogenic Variant(s) Identified: I may learn that I have one or more gene variants known or highly suspected to be associated with a certain disease or illness. Such a result may indicate that I am affected with, have a predisposition for, and/or am a carrier of genetic disorder(s). The finding of a pathogenic variant does not mean I have a 100% certainty of developing disease associated with that gene(s). All positive findings (pathogenic or likely pathogenic variants) should be further discussed with my healthcare provider to evaluate whether further screening or testing is indicated.

b. No Pathogenic Variant(s) Identified: I may learn that no genetic variant for a certain disease or illness was identified. Although this type of result may reduce the likelihood of developing a certain health condition, it does not eliminate the possibility of disease development. This may be due to limitations in current variant knowledge and/or variants in undiscovered genes. Additionally, non-genetic risk factors such as environment, lifestyle and behavior choices may also influence disease development. I acknowledge that further evaluation and/or testing (especially for diseases present in me and/or my family) with my healthcare provider may be indicated.

c. Inconclusive (Variant of Uncertain Significance - VUS): I may learn that I have a VUS in one or more genes. A variant of uncertain significance is a gene change but the significance of this alteration is currently unknown – usually because of limited or conflicting evidence in the medical literature. In the absence of further information, the interpretation of the variant is inconclusive. I acknowledge that the clinical significance of this data is unclear and is subject to further investigation in the course of my medical care. I understand that a VUS may be reclassified to a benign/likely benign and/or pathogenic/likely pathogenic variant in the future, and I may receive updated information from Veritas Genetics in this instance.

d. Disclosure of Carrier Status: I may learn that I am a carrier of one or more genetic disorders. In general, it is expected that variants will be identified in every individual who undergoes WGS. I understand that in most cases this will not have an impact on my own health, but I could be at risk to have a child affected with a genetic disorder. If I am identified as a carrier, further options for screening for myself, my spouse/partner/children/siblings should be considered and discussed with my genetic counselor/ healthcare provider.

7. Incomplete Knowledge. I understand that our collective knowledge of the medical impact of genomic variation is incomplete due to either limited or conflicting evidence in the medical literature. All individuals will have variants with unknown clinical significance in their genomes. One or more of these variants may be reported and discussed with me.

The clinical significance of certain data is still unclear and may become more defined over time. There are gene variants which have yet to be discovered (which may be associated with disease) and will, therefore, not be reported to me at this time. Genetic counseling is available to me to learn more about new developments in WGS, associations of genomic information with diseases or variants and how these changes may impact the understanding of my DNA, and whether further interpretation is desirable.

8. Medical Care. I understand that the data, interpretation and overall results reported by Veritas Genetics is not a substitute for medical care. I will not ignore advice from my genetic counselor, physician or other licensed healthcare provider about such data, interpretation and results. I will not interpret any such data, interpretation and results as recommending or discouraging any specific treatment plan, product or course of action in my medical care.

I am aware that this screening test may identify variants highly suspected of causing serious medical disease which may lead to voluntary medical follow-up in some patients. I acknowledge that the cost of any clinical confirmation and subsequent medical follow-up will be my sole responsibility.

I understand that any medical or health decision should consider more than just genetic screening results and that WGS itself is a rapidly evolving field. Genetic variation can cause or greatly increase the risk of developing specific conditions. These genetic conditions may be inherited within a family. For most other diseases and conditions, genetics contributes only a part of my overall risk. Lifestyle choices and environmental exposures often contribute equal or greater risks to my health. In the same way, not having a genetic risk factor does not mean that I will not develop health conditions.

9. Unperceived Risks. I understand my screening results may help me and my healthcare providers make more informed choices about my health care. However, it is also possible my screening results may reveal information about myself, or my relatives, that I would rather not know. For example, I may learn information about genetic risks/predispositions to disease including ones that might not be curable, biological parentage, ancestry, etc. It may not be possible to prevent learning such information through this screening. I understand I should talk to my physician or genetic counselor about the type of information that I do and do not want to know.

10. Implications for My Family. The Veritas myGenome screening results, like the results of other genetic screening, may have implications for my blood relatives (parents, siblings, children) and particularly if I have an identical (monozygotic) twin. I understand I should speak with my genetic counselor, physician, or other licensed healthcare professional about whether I should share my screening results with others. If I decide to do this, I understand I should consider the best way to communicate this information to them.

11. Genetic Counseling. I understand that genetic counseling is available to me and should be considered before and after this test. My results may prompt additional testing or physician consultation(s). In some cases, test results may lead to testing of other family members. You can find a genetic counselor in your area by visiting the following link: <http://nsgc.org/p/cm/ld/fid=164>. You may also call Veritas Genetics at 888-507-6619 to request an appointment with one of our licensed and board certified genetic counselors.

12. Test Information and Limitations. This WGS test is performed on saliva or whole blood using current, best available high-throughput next generation sequencing technology.

WGS is a relatively new and rapidly evolving field, and test accuracy may change. I understand that current state-of-the-art WGS, including the technology used by Veritas Genetics, cannot provide sequence information for every base in the genome, or for certain kinds of variants.

Certain disease causing variations in the genome cannot be detected using Veritas myGenome technology, and these variations include but are not limited to repeat expansions, certain inversions and deletions, translocations and large structural rearrangements. Therefore, for genetic diseases known to be associated with such mutation types, a disease specific test providing coverage of all necessary mutation types should be considered.

Veritas Genetics is a CLIA certified laboratory, but there is always the small chance an error may occur in any laboratory performing complex screening or testing. Veritas Genetics cannot make any guarantees about the accuracy or completeness of any such data or analysis.

13. Sample Requirement. This test requires saliva or whole blood. In some cases, an additional sample may be requested if the volume, quality, and/or condition of the initial specimen is not adequate.

14. Potential Side Effects of Sample Collection. There are no known significant adverse effects from self-collected saliva. When blood is collected as the source of DNA, adverse effects are rare from routine phlebotomy but may include swelling, soreness, bruising, dizziness, fainting, or infection.

15. Disclosure to your Healthcare Provider. Your genetic data and results will be sent by Veritas to your health care provider. As noted in section 16 below, disclosure may present a risk of discrimination. The interpretation of your genetic data could present or be perceived to present risks different than your motivation to be screened. Additionally, these risks may change as data interpretation will be more advanced in the future.

16. Genetic Discrimination Risks. Genetic information could be used as a basis of discrimination. To address concerns regarding possible health insurance and employment discrimination, many states as well as the federal government in the USA have enacted laws to prohibit genetic discrimination in those circumstances. The laws may not protect against genetic discrimination in other circumstances such as when applying for life insurance, disability insurance, or long-term care insurance. I will talk to my physician or genetic counselor if I have concerns about genetic discrimination prior to screening.

For non-USA patients: It is my responsibility to know the genetic discrimination laws and risks in my country, and I will talk to my physician or genetic counselor if I have concerns about genetic discrimination prior to screening.

17. Electronic Security Risks. The Internet, wireless services, and any electronic storage, including those used by Veritas Genetics, may not be 100% secure. When my information is stored or transmitted there is always a risk that the security on the device or communications may be breached and someone else may then gain access to my screening results or information or re-identify anonymized data as my data.

18. Additional Use of Sample.

Veritas Genetics may store my sample indefinitely except as prohibited by law.

DNA variant(s) identified in my sample may be shared in ClinVar (<http://www.ncbi.nlm.nih.gov/clinvar>) or other similar HIPAA-compliant public databases intended to aid the medical community in the interpretation and diagnosis of genetic disease. In all instances, my data would be de-identified (name and all personal identifying information removed) before this information is shared.

My de-identified sample may be used for new test development and/or laboratory quality assurance purposes by the lab or its collaborators. Additionally, information from my sample may also be used in scientific publications or presentations. I understand that if my sample is used for these purposes, I will not receive any compensation from resulting inventions.

19. Acknowledgement. I acknowledge the following:

- a. I have been offered the opportunity to ask questions and discuss with my healthcare provider/genetic counselor the benefits and limitations of this screening test.
- b. I have discussed with my healthcare provider ordering this screening test the reliability of positive or negative results, and the level of certainty that a positive screening result for a given disease or condition serves as a predictor of that disease or condition. Furthermore, I understand this is a screening test and not a diagnostic test.
- c. I have been informed about the availability and importance of genetic counseling and have been provided with information identifying an appropriate healthcare provider from whom I might obtain such counseling.
- d. I have read this document in its entirety and realize I may retain a copy for my records.
- e. I consent to having this screening test performed and I will discuss the results and appropriate medical management with my healthcare provider/genetic counselor.

I authorize Veritas Genetics to use any remaining sample and test data (with name and all personal information removed) for research, quality improvement and/or publication. Yes No (If a choice is not selected, then "yes" is implied.)

Patient Name (Printed)	Patient Signature	Date (mm/dd/yyyy)
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