

Patient Informed Consent Form for Genetic Testing (Part 1 of 2)

I, _____ request and permit CorePath Laboratories and/or other CAP/CLIA-approved laboratories to analyze the gene(s) indicated on the test requisition form in: My sample My child's sample

I Understand That

1. More information about _____ (condition tested) is available from my healthcare provider.
2. The results of this DNA test could be:
 - a. Positive, and may:
 - i. contribute to the diagnosis of a genetic condition.
 - ii. reveal carrier status for a genetic condition.
 - iii. reveal a predisposition or an increased risk for developing a genetic disease in the future.
 - iv. have implications for other family members.
 - b. Negative, and may:
 - i. reduce but not eliminate the possibility that my condition has a genetic basis.
 - ii. reduce but not eliminate my predisposition or risk for developing a genetic disease in the future.
 - iii. be uninformative.
 - iv. not remove the need for additional testing.
 - c. Of uncertain significance and may:
 - i. lead to a suggestion that testing additional family members may be helpful.
 - ii. remain uncertain for the foreseeable future.
 - iii. be resolved over time. My healthcare provider will be notified of any changes to the classification of previously reported variants that relate to my (my child's) result.
3. Molecular genetic tests may not be diagnostic for the selected condition(s) in all individuals. This test may or may not provide actionable information or have an implication on my medical management.
4. Some types of DNA changes that could cause a specific genetic disorder may not be detected by this test. As with most molecular genetic tests, the assay performed on your sample has technical limitations that may prevent detection of specific rare variants due to poor DNA quality, inherent DNA sequence properties, or other types of limitations.
5. CorePath and/or its partner genetic testing laboratory follow best laboratory practices; however, there may be possible sources of error including, but not limited to, trace contamination, rare technical errors in the laboratory, rare DNA variants that compromise data analysis, inconsistent scientific classification systems, and inaccurate reporting of family relationships or clinical diagnosis information.
6. CorePath and/or its partner genetic testing laboratory will interpret the parts of the DNA sequence of gene(s) indicated on the requisition form by my or my child's physician. However, the technology obtains the DNA sequence information related to a broad range of genetic conditions and interpretation and release of other parts of the remaining genetic data can be requested through my healthcare provider (additional charges may apply).
7. CorePath's clinical reports are released only to the healthcare professional(s) listed on the test requisition form. Clinical reports are confidential and will only be released to other medical professionals with my explicit written consent.
8. It is my responsibility to consider the possible impact of my or my child's test results as they relate to insurance rates, obtaining disability or life insurance and employment. The Genetic Information Nondiscrimination Act (GINA), a federal law, provides some protections against genetic discrimination. For information on GINA visit <http://www.genome.gov/10002328>.

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9. Results from the genetic test are analyzed with the assumption that correct information on family relationships has been provided. Due to the type of test performed there is the possibility that inconsistencies in information on family relationships could be identified if multiple family members are tested. For example, this test may detect misattributed paternity, where the stated father of an individual is found to not be the true biological father. It may be necessary to report these findings to an individual who requested testing.

10. I will be offered genetic counseling with a geneticist, genetic counselor or other qualified healthcare provider who can answer questions, provide information and advise about alternatives before and after having this test. Further testing or additional physician consults may be warranted.

11. My (my child's) data and personal information will be stored and protected in strict confidence complying with regulatory requirements (e.g. HIPAA and equivalent protections), and acknowledge that I have read and understand CorePath's Notice of Privacy Practices, which can be found on www.corepath.us. My (my child's) individually identifiable health information (i.e., "Protected Health Information" under HIPAA) will NOT be used in FOR PROFIT research without my additional, explicit consent.

12. Because the understanding of genetic information will improve over time, my healthcare provider may notify me of clinical updates related to my (my child's) genetic profile (in consultation with my primary clinician as indicated).

13. I have the right to receive a copy of this consent form.

By Signing Below, I Attest to the Following

1. I have been informed of the likelihood of finding a change in the gene(s) for which I, or my child, am being tested and have received test-specific clinical information.

2. I have read and understand the information provided on this form and have had an opportunity to have any questions answered by my healthcare provider.

Patient Signature _____ Date _____

Patient Name (Please Print) _____

Parent/Guardian Signature, if Patient is a Minor _____ Date _____

Parent/Guardian Name (Please Print) _____

Healthcare Provider Statement

By signing below, I attest that I am the referring physician or authorized healthcare professional. I have explained the purpose of test described above. The patient has had the opportunity to ask questions regarding this test and/or seek genetic counseling. The patient has voluntarily decided to have this test performed by CorePath and/or its partner genetic testing laboratory.

Health Provider Signature _____ Date _____