

Informed Consent for Panel Genetic Testing

I, _____ (full name) request and permit Invitae to analyse the gene(s) indicated on the test requisition form in: My sample

I UNDERSTAND THAT:

1. More information about _____ (condition tested) is available from my healthcare provider and can also be found on the Invitae website (www.invitae.com).
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 (Variant of Uncertain Significance or VUS) 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, Invitae's test 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. 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. Invitae will only 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. Invitae's clinical reports are released only to the certified 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. It has been explained to me that my clinical report is available for me to view or download at the Invitae website (www.invitae.com) after it has been released by my healthcare professional(s). Alternatively, my clinical report can be made immediately available upon completion of the test with the prior approval of my healthcare professional, as indicated on the test requisition form.
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>.
9. Results from the Invitae test are analysed 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.

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10. I will be offered pre and post-test clinical support via Everything Genetic's digitised service. Should the patient wish to speak with a genetic consultant pre-test who can answer questions, provide information, and advise about alternatives, this can be arranged at the Company's discretion. Patients who test positive will each receive one-to-one clinical support. 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 [Invitae's Privacy Policy](#)* and [Notice of Privacy Practices](#)** 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, Invitae may notify me of clinical updates related to my (my child's) genetic profile (in consultation with my primary clinician as indicated). I may request additional notifications and resources relevant to my genetic profile by creating an account at www.invitae.com/patients.
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)	Email address	

HEALTHCARE PROVIDER STATEMENT

By signing below, I attest that I am the referring physician or authorised 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 Invitae.

Healthcare provider signature		Date
Healthcare provider name (please print)		

*Invitae's Privacy Policy can be found at www.invitae.com/en/privacy-policy/

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