Picture
By Fulgent Genetics

Picture Genetics Informed Consent for Genetic Testing

I authorize Fulgent Genetics to test my sample (or my child's sample). I understand that Picture Genetics is a service provided by Fulgent Genetics, and that Fulgent or its subsidiaries will perform the testing. I further understand and agree to the following:

RISKS

1. DNA testing requires a buccal swab or saliva sample. Occasionally, additional samples may be needed if the sample was insufficient, damaged in shipment, or inaccurately submitted.

2. I authorize Fulgent to release the medical information concerning my testing to my insurance company if the testing is billed through my insurance, to the extent allowed by law. The Genetic Information Nondiscrimination Act (GINA) prohibits genetic discrimination with respect to health insurance and employment. However, GINA does not apply to life, disability, or long-term care insurance, which may be governed by state or international laws, depending on where I live.

3. I may learn genetic information about myself or my family, including reproductive implications and risks for diseases that do not have current treatment. I may also learn information unrelated to the medical concern for which this test was ordered. This may cause anxiety, stress, identification of at-risk family members or misattributed parentage, and difficulty obtaining life and disability insurance.

4. For Picture Newborn, this information may reveal: genetic risks for diseases that may develop later in life, or disorders that have limited treatment or no cure at this time. Additionally, it is important to note that approximately 3-5% of all babies have a birth defect due to a wide variety of factors. A negative test result on this test does not reduce this background risk and does not mean that a child is not at risk of developing a certain genetic condition.

5. For Picture Parenting, this test is designed to identify individuals or couples that are at risk of having a child with an autosomal recessive or X-linked genetic disorder. It is important to note that a negative test does not rule out the possibility of a risk to have a child with a genetic condition, birth defect, or developmental disorder. In rare cases, the test may reveal genetic health risks for the individual being tested.

6. For Picture PD Aware and Picture Wellness tests, this information may reveal: genetic risks for diseases that may develop later in life; disorders that have limited treatment or no cure at this time, or diseases unrelated to the primary reason for ordering the test.

7. For Picture PGx tests, results may have implications for my metabolism of certain drugs. I understand that I should follow up with my healthcare provider to discuss my results, and that no changes to my medication plan should be made without consultation with my healthcare provider. Positive results do not imply that there are no other contributors, genetic or otherwise, to my phenotype, and a negative result does not rule out a genetic cause for the indication for testing.

LIMITATIONS

1. Genetic testing is complex. While Fulgent takes extensive measures, technical, biological, and systematic errors may still occur. I or my provider will be notified if such errors are discovered.

2. Fulgent is authorized under Clinical Laboratory Improvement Amendments (CLIA) and College of American Pathologists (CAP) to perform high-complexity testing. This test is not FDA-approved, and FDA approval is not currently required.

3. Results should be interpreted in the context of clinical findings, biochemical profile, family medical history, and reported biological relationships. Reporting errors can lead to incorrect results. Results may further be inaccurate if I had a blood transfusion or bone marrow or stem cell transplant.

4. This analysis is specific only for the test ordered. This test will not detect all variants or, if applicable, all mutations possible within the gene/panel of genes evaluated. There are some types of DNA changes that cannot be detected by the requested test; and there are some disease-related DNA changes which are outside the region of the genome that is queried by this test. Fulgent or a medical provider may recommend additional testing but are not obligated to do so.

REPORTING

1. As applicable, results may have clinical or reproductive implications for my child and/or my/their biological relatives. Participation is voluntary. I may want to seek professional genetic counseling prior to signing this form and after receiving my test results.

2. I must follow up with my primary care physician to discuss my results and to consider whether to pursue additional genetic testing or genetic counseling. A positive result means that a pathogenic or likely pathogenic variant was identified. A negative result does not rule out pathogenic variants in areas not assessed or in regions that were covered at a level too low to reliably assess.

3. No test other than the test that was authorized shall be performed on the biological sample. Fulgent is not obligated to report results for tests I did not order or to rule out variants not queried.

4. Because of the complexity of genetic testing and the implications of the test results, results will also be reported to the ordering provider. Fulgent does not render a diagnosis or prescribe treatment. If I chose to work with a healthcare provider, complimentary genetic counselor (if offered), ordering provider, or physician (collectively, "Provider"), I authorize Fulgent and Provider to discuss my case and share my personal information, health information, family history, and test results.

5. My test results are confidential and will only be released to other medical professionals or other parties with my written consent, per Fulgent's privacy policy. All laboratory raw data is confidential and will not be released unless consented to, allowed by law, or with a valid court order.

6. The interpretation of the test results will be based on the laboratory's current information at the time of analysis. As medical knowledge advances, and new discoveries are made, the interpretation may change. It is possible that re-interpretation of results could lead to new information about potential medical conditions. Such reinterpretation must be requested by a physician and will involve additional costs. A new sample may be required. Fulgent may choose to provide an updated report or recommend re-interpretation in the future but is under no obligation to do so.

SAMPLE RETENTION

1. Samples will not be returned and will be either destroyed or retained in the laboratory in accordance with applicable laws and regulations and Fulgent's retention policy. For saliva/buccal swabs and blood samples, used swab tubes or remaining blood specimens will be retained for 90 days after issuance of the final test result. At that time, used swab tubes will be discarded, and blood samples may be discarded or stripped of all identifiers (except for age and gender) and used for quality control purposes.

[ ] I opt in to storage of my sample for a longer duration of 90 days. (New York residents only).
[Note: All samples from New York patients will be destroyed within 60 days after Fulgent's receipt of the sample (or upon completion of the testing), unless you opt in above].

2. It may be possible to perform further studies on the remaining sample. My Provider or I must expressly request additional studies, subject to potential additional charges.

RESEARCH CONSENT

1. Fulgent may contact me about research opportunities, research findings, or my testing experience. I can opt out of being contacted by emailing privacy@picturegenetics.com.

2. As long as my privacy is protected, I can choose to consent to having my de-identified sample be used for medical research or educational purposes. If used for research, my de-identified sample may be stored indefinitely without being attributed to me. I understand that my refusal to consent to research will not affect my test results. I can withdraw my consent at any time by contacting Fulgent's laboratory director at clientservices@fulgentgenetics.com

[ ] Yes
[ ] No
My de-identified data can be used for research. (Consent is implied if neither box is checked).

NATURE, PURPOSE, AND DESCRIPTION OF THE TEST

1. Genetic Sequencing is the process for evaluating the "clinical" or "medical" exome, defined as the subset of known protein coding genes, which have been associated with a medical condition. It is an efficient means to achieving molecular diagnosis where standard medical evaluation is not sufficient.

2. During the testing process, genomic DNA is isolated from the submitted specimen. DNA is barcoded and enriched for the coding exons of targeted genes using hybrid capture technology. DNA libraries are prepared, then sequenced using a Next Generation Sequencing technology.

3. Following alignment, variants are detected. Variants may be interpreted manually using locus specific databases, literature searches, and other molecular biological principles and interpreted according to the American College of Medical Genetics and Genomics guidelines. All the variants with quality score less than 500 are confirmed by sequencing. Only variants classified as pathogenic, likely-pathogenic, or unknown significance (if thought to be related to the patient's phenotype or test indication) are reported.

4. All genes listed are evaluated for large deletions and/or duplications. However, single exon deletions or duplications will not be detected in this assay, nor will copy number alterations in regions of genes with significant pseudogenes. Putative deletions or duplications identified are confirmed by an orthogonal method (qPCR or MLPA). When a single pathogenic or likely pathogenic variant is identified in a gene with autosomal-recessive inheritance, the laboratory ensures that 100% of coding sequences of that gene are covered either through NGS or Sanger sequencing technologies.

ACKNOWLEDGMENT OF INFORMED CONSENT

1. By signing below, I acknowledge that I have read and understood this form.

2. I consent to the genetic analysis of my sample by Fulgent, as ordered by an authorized Provider.

3. I consent to the collection, storage, electronic transfer, and processing of my personal and health information, including any necessary transfer across national borders (if applicable).

4. I also consent to the analysis of the obtained sample and its storage at Fulgent, in accordance with Fulgent's specimen retention policy, together with my patient file to be able to verify results of the analysis if need be. I authorize Fulgent to inform me or my Provider about the results of the genetic analysis and, upon request, to provide to me or my physician the raw data of the genetic analysis.

5. I am at least 18 years old, have legal authority to sign this form, and (if applicable) was advised that certain genetic testing on minors is not recommended. I had the opportunity to ask questions.

6. This test is intended to inform me of my (or my child's) genetic risk or impact related to the genes tested; it is not intended to diagnose whether or not I (or my child) have or will develop a condition. Medical decisions should not be made based on test results without first speaking to a physician.

7. I am awarwe that I can withdraw my consent in full or in part, and that I have the right not to know the results of the genetic analysis performed.

8. Participation in this test is entirely voluntary but in no way releases Fulgent and its staff from their professional and ethical responsibilities.

_____ **[Name]** _____ **[Date]**

