BAYLOR GENETICS

BAYLOR GENETICS
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GRAND BLVD. RECEIVING DOCK
HOUSTON, TX 77021-2024

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CONNECT

INFORMED CONSENT FOR GENETIC TESTING

Patient Last Name	Patient First Name	MI	Date of Birth (MM / DD / YYYY)	Genetic Sex
			/ /	

TEST INFORMATION

This consent form will provide you with information regarding genetic testing, which you should discuss with your healthcare provider or a genetic counselor. To assist you in understanding the reason for this testing, we have provided information about the testing process and potential results below.

The purpose of genetic testing is to determine if a genetic disease may be present or if there is an increased risk for a genetic disease to occur in a patient or their family. DNA is the genetic material that we receive from our parents. Genes are made of DNA and are the instructions for maintaining the health of our body. Each person has a unique set of DNA and most of the differences in our DNA do not impact our health. Genetic testing analyzes DNA to find any abnormal changes (mutations also called variants) that might cause disease, make it more likely to develop disease, and/or increase the chance of having a child affected by disease.

The testing ordered by your healthcare provider can determine if you or your child have a variant associated with a genetic disease. "Your child" can also mean your unborn child, for the purposes of this consent.

Depending on why genetic testing is needed, you might be tested for:

- A known variant that has already been found in your family
- A single gene or variant that causes a specific, suspected disease.
- Multiple genes at the same time. These genes might cause similar diseases or might cause diseases that are unrelated to each other.
- Multiple types of testing that each test for different variants.

RESULTS

There are several types of test results that may be reported including:

- Positive: Positive or "abnormal" results mean there is a change in the DNA found that is related to your/your child's medical issues or that you/your child are at an increased risk of developing a disease in the future. It is possible to test positive for more than one variant. Positive results might include pathogenic variants (variants known to be associated with disease) and likely pathogenic variants (variants that are likely to be associated with disease).
- Negative: Negative or "normal" results mean no relevant variants related to your/your child's medical issues were detected or that you/your child are not expected to be at an increased risk for developing a disease in the future. This might indicate that there are no variants associated with disease in the gene(s) tested. Genetic testing, while highly accurate, might not detect a variant present in the gene(s) tested. This can be due to limitations of the information available about the gene(s) being tested, or limitations of the testing technology.
- Variant of Uncertain Significance: Testing can detect variant(s) in DNA which we do not yet fully understand. These are also referred to as variants of uncertain significance (VUS). Additional testing may be recommended for you or your family if a VUS is identified in a gene that may be associated with your/your child's medical condition.
- Secondary / Incidental Findings: Testing can sometimes detect a variant in a person's DNA unrelated to the reason for testing. If this variant is expected to have medical or reproductive significance, it is called a secondary or incidental finding.

CONSIDERATIONS AND LIMITATIONS

- This consent form cannot be used for whole exome sequencing (WES), whole genome sequencing (WGS), or Huntington's disease testing. These tests have specific consents that are located at https://www.baylorgenetics.com/consent/.
- Results may indicate you have a genetic disease, are at increased risk to develop a genetic disease, and/or be at an increased risk to have a child with a genetic disease. It is important to understand that genetic tests, even if negative, cannot rule out every variant. It is not possible to exclude risks for all genetic diseases for you and your family members.
- Depending on the type of genetic testing performed and the results, additional genetic testing or other testing may be needed to fully understand the likelihood of your developing the disease or the severity of the disease. This additional testing might be needed for you/your child or other members of your family.
- It is recommended that you discuss genetic testing with your healthcare provider or genetic counselor before signing this consent and again after results are made available.
- It may not always be possible to complete testing. as sometimes the sample does not have enough DNA to perform testing or other reasons. In these cases, another sample may need to be sent to the laboratory to perform testing.

PATIENT CONFIDENTIALITY AND SPECIMEN RETENTION

- If several family members are tested, the correct interpretation of the results depends on the information provided about the relationships amongst family members. In rare cases, genetic testing can reveal that the true biological relationships in a family are not as they were reported. If a difference is identified, it may be necessary to share this information with the healthcare provider who ordered the testing.

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PATIENT CONFIDENTIALITY AND SPECIMEN RETENTION (CONT.)

- Genetic testing is highly accurate, however in rare cases, inaccurate results may occur. Reasons for this include, but are not limited to, mislabeled samples, inaccurate reporting of clinical/medical information, or rare technical errors.
- If you sign this consent form, but you no longer wish to have your sample(s) tested, you can contact the healthcare provider who ordered the test to cancel the test. If you wish to cancel testing, the laboratory must be notified of the cancellation request before 5 PM CST the business day after the sample has begun testing. If the laboratory is not notified of your cancellation request until after this time, you will be charged for the full cost of the test.
- Only Baylor Genetics and Baylor Genetics contracted partners will have access to the sample(s) provided to conduct the requested testing. Results will only be released to the following person(s): (i) a licensed healthcare provider, (ii) those authorized in writing, (iii) the patient or their personal representative, and (iv) those allowed access to test results by law. I understand that I have the right to access any test results directly from Baylor Genetics by providing a written request. I also understand that laboratory raw data, while not routinely released as part of the testing process, can be requested by providing a written request or HIPAA Authorization Form.
- In rare cases, persons with genetic diagnoses have experienced problems with insurance coverage and employment. The U.S. Federal Government has enacted several laws that prohibit discrimination based on genetic test results by health insurance companies and employers. In addition, these laws prohibit unauthorized disclosure of this information. For more information, you can visit www.genome.gov/10002077.
- Samples will be retained in the laboratory in accordance with the laboratory retention policy.
- After testing is complete, the de-identified submitted specimen may be used for test development and improvement, internal validation, quality assurance, and training purposes. DNA specimens are not returned to individuals or to referring heath care providers unless specific prior arrangements have been made.
- Samples from residents of New York State will not be included in research studies without your written consent and will not be retained for more than 60 days after receipt of the sample. No tests other than those authorized shall be performed on the biological sample.
- By signing this consent form, I understand and agree that variants identified may also be submitted to public databases, such as ClinVar. Such submission serves to contribute knowledge to the medical community. I understand that limited clinical information is also required for the submission of information to ClinVar's database and further that the contents of this limited clinical information may, although unlikely, include information that may identify me personally.
- It is possible that even if the test identifies the underlying genetic cause for the disease in your family, this information may not help in predicting the progression of disease or change management or treatment of disease.

FINANCIAL AGREEMENT AND GUARANTEE

By signing this consent form, I accept full and complete financial responsibility for all genetic testing ordered by my healthcare provider. For insurance billing, I hereby authorize Baylor Genetics to bill my health insurance plan on my behalf, and further authorize Baylor Genetics to release any information to my insurance carrier which is reasonably required for billing. I additionally designate Baylor Genetics as my designated representative for purposes of appealing any denial of benefits by my insurance carrier. I irrevocably assign associated payment to Baylor Genetics, and direct that payment be made directly to Baylor Genetics. I understand that my out-of-pocket costs may be different than the estimated amount indicated to me by Baylor Genetics as part of a verification of benefits investigation. I agree to be financially responsible for all amounts as indicated on the explanation of benefits issued by my health insurance plan. If my insurance provider sends a payment directly to me for unpaid services performed by Baylor Genetics on my behalf, I agree to endorse the insurance check as appropriate and forward such check to Baylor Genetics within thirty (30) days of receipt thereof, as payment towards Baylor Genetics' claim for services rendered. If I do not have health insurance, I agree to pay for the full cost of the genetic testing that was ordered by my healthcare provider and billed to me by Baylor Genetics.

I understand that a completed Advance Beneficiary Notice (ABN) is required for Medicare patients if the service is deemed not medically necessary.

RECONTACT FOR RESEARCH CONSENT

Baylor Genetics participates in research relating to health, disease prevention, drug development, and other scientific purposes. Baylor Genetics may contact patients or their provider(s) directly as part of this research. I agree to allow Baylor Genetics to contact me or my provider(s) about possible research involving the sample(s) and/or information associated with this testing. I understand that patients generally receive no compensation for this participation in research. For more information on research at Baylor Genetics, please visit baylorgenetics.com.

If I wish to opt out of being recontacted for research purposes by Baylor Genetics, I understand that I may check the box below:

☐ Please do not contact me regarding any research that uses information obtained from this testing.

For any research I may be contacted about, I prefer contact through the following methods (please check all that apply – if no choices are selected, contact will be made via secure email if possible):

☐ Email ☐ Phone ☐ Mail

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PATIENT AUTHORIZATION

By signing this statement of consent, I acknowledge that I have read, understand, and hereby grant my informed consent for genetic testing. I have received appropriate explanations from my healthcare provider about the planned genetic test(s) and possible results. I have been informed by my healthcare provider about the availability and importance of genetic counseling and have been provided with written information identifying a genetic counselor or medical geneticist who can provide such counseling services. All my questions have been answered and I have had the necessary time to make an informed decision about the genetic test(s).

I hereby give permission to Baylor Genetics to conduct genetic testing as recommended by my physician.

Patient's Printed Name	Patient's Signature	Date (MM / DD / YYYY)
		/ /
Patient's Parent / Personal Representative* Name	Patient's Parent / Personal Representative Signature	Date (MM / DD / YYYY)
		/ /
Relationship of Personal Representative to the Patient	Ordering Provider's Signature	Date (MM / DD / YYYY)
		/ /

*If you are signing as a person with legal authority to act on behalf of the patient, you may be required to provide evidence of your authority.