BAYLOR GENETICS

BAYLOR GENETICS
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INFORMED CONSENT FOR RNA SEQUENCING (RNASEQ) GENETIC TESTING

Patient Last Name _____ Patient First Name _____ MI _____ Date of Birth (MM/DD/YYYY) ____ / ____ / ____

TEST INFORMATION

This consent form will provide you with information regarding RNA Sequencing (RNAseq) 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 this testing is to provide additional information about the results obtained from Whole Exome Sequencing (WES) or Whole Genome Sequencing (WGS). WES/WGS may identify changes, called variants, within one or more genes. Based on available scientific knowledge, the clinical significance of one or more of the identified variants may not be clear from WES/WGS alone. These variants are called variants of uncertain clinical significance (VUS).

For VUS that meet certain criteria (qualified variants), a comprehensive analysis of the RNA can be performed by RNAseq. RNA is made from DNA and is used by the body to create many different proteins. RNAseq can help clarify if the qualified variant(s) being assessed are clinically significant. It is possible that even if RNAseq identifies additional information it may not be enough to clarify the clinical significance of any or all qualified variants. After you have received your results, you should discuss the significance of these results with your healthcare provider or genetic counselor.

RESULTS

The results of RNAseq may help to clarify the clinical significance of one or more variant(s) identified via WES/WGS. Information from RNAseq will be included in an updated version of your WES/WGS report.

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

- Reclassification of the variant to pathogenic/likely pathogenic ("upgrade"): One or more previously identified variant(s) are now classified as pathogenic (known to be associated with disease) or likely pathogenic (likely to be associated with disease). These variants are now considered to be related to your/your child's medical issues or indicate that you/your child are at an increased risk of developing a disease in the future.
- Reclassification of the variant to benign ("downgrade"): One or more previously identified variants are now classified as benign (unlikely to be associated with disease). These variants are now considered unrelated to your/your child's medical issues and not expected to be associated with an increased risk of developing a disease in the future. These variants will be removed from the updated report.
- Classification remains the same: One or more previously identified variant(s) was not able to be upgraded or downgraded. These variants are still classified as of uncertain clinical significance, and their association with current or future disease is unclear. Additional testing may be recommended to further clarify the clinical significance of these variants.

CONSIDERATIONS AND LIMITATIONS

- This consent form can only be used for RNAseq. Consent forms for other tests are located at Baylor Genetics' website (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.
- 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.
- 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 you/your child 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 and will be discussed by your healthcare provider.
- 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 RNA to perform testing or other reasons. In these cases, another sample may need to be sent to the laboratory to perform testing.
- In many instances, WES/WGS will not identify a qualified variant. If no qualified variant is identified by WES/WGS, RNAseq will not be performed.

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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 among 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.
- 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/your child's 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 been received by Baylor Genetics. 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 my test results directly from Baylor Genetics by providing a written request. I also understand that laboratory raw data 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. RNA specimens are not returned to individuals or to referring healthcare providers unless specific prior arrangements have been made.
- Samples from residents of New York State will not be included in general research studies without your written consent and will not be retained for more than 60 days after receipt of the sample, unless specifically authorized by your selection below. No tests other than those authorized shall be performed on the biological sample.

FOR SAMPLES SUBMITTED FROM NEW YORK STATE

_____ Initial

I understand that no genetic test other than those I have authorized shall be performed on my biological sample, and the sample will be destroyed at the end of testing or not more than 60 days after the sample was taken. However, by initialing here, I hereby authorize the lab to retain my sample(s) for longer retention in accordance with the laboratory retention policy for internal laboratory quality assurance studies and possible research testing.

- By signing this Consent form, I understand and agree that information 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 or members of my family.

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.

If my health insurer does not cover the test or I do not have health insurance, I have received a good faith estimate of the cost for the genetic testing ordered by my provider and agree to pay for the cost of the genetic testing billed to me by Baylor Genetics based on that good faith estimate. More information is available in Baylor Genetics' No Surprises Act and Good Faith Estimate Notice located at: https://www.baylorgenetics.com/no-surprises-act/.

I understand that a completed Advance Beneficiary Notice (ABN) is required for Medicare fee for service patients if the service is not payable by Medicare as not medically necessary or reasonable.

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 directly as part of this research. I agree to allow Baylor Genetics to contact me 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 via secure email will be made if an email address is provided):

☐ 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 Name	Patient's Signature	Date Signed (MM / DD / YYYY)
		____ / ____ / ____

Patient's Parent / Personal Representative* Name	Patient's Parent / Personal Representative Signature	Date Signed (MM / DD / YYYY)
		____ / ____ / ____

Relationship of Personal Representative* to the Patient

Ordering Provider's Signature	Date Signed (MM / DD / YYYY)
	____ / ____ / ____

*If you are signing on behalf of the patient as the parent(s) and/or person with legal authority to act on behalf of the patient, you may be required to provide evidence of your authority.