BAYLOR GENETICS

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GENEAWARE CONSENT FORM

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

GENEAWARE CONSENT FORM

TEST INFORMATION

The purpose of this consent form is to provide you with information regarding the GeneAware test (version 3, 421 genes). However, it should not take the place of discussing this information with your healthcare provider and/or genetic counselor. The purpose of the GeneAware reproductive carrier screening test is to determine if you are a carrier of a pathogenic variant for a genetic disorder. A pathogenic variant is meant to refer to both pathogenic and likely pathogenic variants. Everyone is a carrier for several genetic disorders but may not know their risk, especially if there are no affected family members. Disorders screened for by the GeneAware panel test focus on genetic conditions that present early in life, some may have treatment options available and others may not. If you are found to be a carrier, you can discuss with your healthcare provider or genetic counselor next steps regarding additional testing and family planning options.

RESULTS

The categories of test results that may be reported include:

- Positive, pathogenic variant/s detected. This means you are a carrier of a pathogenic variant for a genetic disorder. You may be a carrier for more than one genetic disorder.
- Positive, two pathogenic variants detected in the same gene. Rarely a patient may have two pathogenic variants for one genetic disorder. The two pathogenic variants may be in the same copy of the gene; alternatively, one of the variants may reside in one copy of the gene and the other variant may reside in the other copy of the gene. The configuration of pathogenic variants affects the reproductive risk calculation. If the pathogenic variants are in opposite copies of the gene, it is also possible that the patient could have clinical symptoms of the disorder or could be at risk to develop symptoms of the disorder. It is usually necessary to test additional family members in order to establish the configuration of pathogenic variants.
- Negative, no pathogenic variant detected in the genes examined by this test. There is still a small chance that an examined gene may contain a pathogenic variant that is not detectable by the methodology used. Different genes may produce similar disorders. It is therefore possible to be a carrier for a condition due to the presence of a pathogenic variant in a gene that is not included in this GeneAware panel.

INFORMATION AND CONSENT FOR TESTING

- The purpose of this test is to assess reproductive risk for conditions caused by pathogenic changes in the genes examined by this test. However, testing can reveal sensitive health information about you and/or your partner. Additionally, test results can have health implications for members of your immediate family. This information may also reveal unexpected information, such as evidence of extra or missing sex chromosomes.
- A negative result reduces but does not completely eliminate your risk to be a carrier for the tested conditions.
- GeneAware does not rule out being a carrier for disorders that are NOT included on the GeneAware panel.
- This test is not for diagnostic purposes. The GeneAware carrier screening does not report variants of uncertain significance (VUS) or certain mildly pathogenic variants that are very common in the general population. If you suspect that you are affected with a genetic disorder, diagnostic testing specific for that disorder should be used.
- If there is a known family history for a specific genetic disorder listed on this test and your result is negative, it does not necessarily mean that you are not a carrier of a pathogenic variant for that particular disorder. Testing of affected family members first in order to identify pathogenic variants carried in the family is ideal. If an affected family member is not available for testing, or if information cannot be communicated, specific full gene sequencing may be recommended.
- This test is not for prenatal diagnostic purposes. This test is only meant to determine pathogenic variant carrier status for you. If you are determined to be at high risk of having an affected child, then gene-specific prenatal diagnostic testing may be considered. Prenatal diagnostic testing is available for all of the disorders on the GeneAware panel.
- This test will detect most pathogenic changes in the examined genes in most populations. The detection rate varies by gene and ethnicity. Some ethnicities or subpopulations may have an increased frequency for a specific pathogenic variant that cannot be detected by this assay.
- This testing is complex and utilizes specialized materials. There is a very small possibility that the test will not work properly or that an error will occur.
- Results will only be released to a licensed healthcare provider, to those allowed access to test results by law, and to those authorized in writing.
- Samples will be retained in the laboratory in accordance with the laboratory retention policy.
- Information including results, indications for testing and clinical status obtained from the GeneAware carrier screening test may be shared with healthcare providers, scientists and healthcare databases or used in scientific publications or presentations, but the personal identifying information of all persons studied will not be revealed in such data sharing or publications/presentations.

FOR NY PATIENTS: 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 unless I authorize otherwise below.

RESEARCH & RECONTACT CONSENT

For more information on research at Baylor Genetics, please visit baylorgenetics.com. Please read the below statements carefully and check the appropriate box.
Note: If left blank, consent is interpreted as "NO."

☐ I agree to use of my de-identified specimen for research to improve genetic testing for all patients and contribute to scientific research.

☐ I am a New York State Resident, and I give Baylor Genetics permission to store my specimen in accordance to the laboratory retention policy for internal quality assurance and possible research studies.

☐ In addition to agreeing above, I agree to be contacted by Baylor Genetics regarding research opportunities.

PATIENT AUTHORIZATION

My medical provider has presented this test as an option to assess my reproductive risk for certain genetic conditions. The results of this test may impact my medical care and the availability of reproductive options. The person listed as the Ordering Physician is authorized by law to order the test(s) requested herein. I confirm that I have reviewed this information with my care provider and I consent to genetic testing.

Patient Signature	Date (DD/MM/YYYY)

Printed Name