BAYLOR GENETICS
READY WITH ANSWERS

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GENEAWARE CONSENT FORM

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

GENEAWARE CONSENT FORM

TEST INFORMATION

The purpose of this consent form is to provide you with information regarding the GeneAware test, however it should not take the place of discussing this information with your healthcare provider. 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. 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 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 then 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 sometimes 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 partnerAdditionally, 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 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, then 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 in the event that 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 to have 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 so that there is always a very small possibility that the test will not work properly or that an error will occur.
- Samples will be retained in the laboratory in accordance with the laboratory retention policy.
- Information obtained from the GeneAware carrier screening test may be used in scientific publications or presentations, but the identity of all persons studied will not be revealed in such publications/presentations.

STATEMENT OF MEDICAL NECESSITY

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 (MM/DD/YY) ___ / ___ / ___

Printed Name _____

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