revvity

Informed Consent Form - NEW YORK

Individuals having samples collected in New York State must also complete this page.

Patient's Name: _____ **Patient's Date of Birth:** mm/dd/yyyy

When signed and dated below, this written consent is written authorization to participate in genetic testing.

1. **General Description and Purpose of the Test:** My (or my child's) healthcare provider has explained that the recommended testing (name of tests or Revvity test codes) _____, will be performed to help inform a diagnosis of the following conditions or diseases (insert description of condition or disease) _____. My (or my child's) healthcare provider has explained to me, to my satisfaction, the purpose and methodology of, and the disorders or conditions associated with, the recommended testing. I am aware that additional information regarding this testing, including its purpose, methodology, and associated disorders or conditions is available at https://www.revvity.com and I have had the opportunity to review this information to my satisfaction with my (or my child's) healthcare provider or on my own. **Patient (or Parent/Guardian) initials: _____.**

2. **Availability of Genetic Counseling.** I have been provided with information about obtaining professional genetic counseling prior to giving my consent for this testing. I further understand that my (or my child's) healthcare provider may recommend consultation with a medical geneticist, genetic counselor and/or a physician after the testing is completed.

3. **Test Limitations.** I understand that, due to current limitations in technology and incomplete knowledge of diseases and genes, some gene variants may not be detected by the test ordered. I further understand that it is a possibility that the test result is uninterpretable or deemed of unknown significance and that additional testing may be recommended by my (or my child's) healthcare provider. As with any laboratory test, there also is a possibility of error.

4. **Positive Test Results.** I understand that a positive result may indicate that I am (or my child is) a carrier of, I (or my child) may be predisposed to, or I (or my child) may have, the specific diseases or conditions for which I am consenting to being tested (or having my child tested). I understand that, in consultation with my (or my child's) healthcare provider upon receipt of my (or my child's) results, I may wish to consider further independent testing, or pursue genetic counseling. I further understand that my (or my child's) healthcare provider is responsible for communicating with me regarding the results of my (or my child's) testing and may refer me (or my child) to a specialist for further clinical evaluation or laboratory testing, as applicable.

5. **Negative Test Results.** A negative test result indicates that the clinically significant variant test was not detected. Negative results may also be due to: (a) maternal contamination of prenatal samples; (b) technical reasons (e.g., poor sample quality); and/or (c) the need to test other family members. I have discussed with my (or my child's) healthcare provider information about the detection rate for the disease(s) or condition(s) for which I am (or my child is) being tested and I understand that a negative result does not guarantee that I do (or my child does) not have or will not develop the disease / condition for which testing was performed.

6. **Level of Certainty.** I understand that the ability of a genetic test to provide risk information and the level of certainty that a positive result is an indicator that I have (or my child has) the disease or condition for which I am (or my child is) being tested may vary with the type of testing performed. If applicable, I have been provided with information about the level of certainty regarding a positive result for the above specified testing. In addition, I understand that the level of certainty regarding a positive result may be determined or affected by the testing methods employed, my (or my child's) clinical history, my (or my child's) health at the time of sample collection, and sometimes by the manner in which my sample was collected. Additionally, I understand that there is always a small possibility of error or failure in the sample analysis; and that this is true with complex testing in any laboratory.

7. **Disclosure of Test Results.** I understand that the categories of persons or organizations to whom Revvity may release my (or my child's) test results include, but are not necessarily limited to: hospitals and other laboratories involved in my (or my child's) care, referring or ordering health care providers, primary care providers, other physician groups, insurance companies, and other professionals involved in patient care that assist Revvity in carrying out treatment, payment, and healthcare operational activities. I understand my (or my child's) results will be kept confidential and that Revvity complies with applicable security and privacy laws. I understand that if I wish to specifically authorize to whom my (or my child's) results may be disclosed, I should provide written instructions to Revvity by contacting genomics@revvity.com.

8. **Consent to Retain Specimen.** I understand that: Revvity does not return any remaining sample to individuals or physicians unless requested; no clinical tests other than those authorized shall be performed on my (or my child's) sample; and any request for additional testing must be made by my referring physician or other authorized healthcare provider at additional charge. I further understand that under New York State law, my (or my child's) sample shall be destroyed at the end of the testing process or not more than sixty (60) days after the sample was taken, unless I expressly authorize a longer period of retention in this consent form.

   ❑ **By checking this box and signing below, I consent to Revvity keeping my (or my child's) biological sample indefinitely and to using my (or my child's) de-identified sample for research, assay validation, instrument evaluation, and other quality assurance purposes. Note, if this box is not checked, this will be interpreted as "patient consent not given."**

   If I have consented to such retention by checking the box above, I understand that I may withdraw this consent at any time by contacting genomics@revvity.com.

9. **Testing for Genetic Conditions may be Complex.** I understand that, if I have any remaining questions about the recommended genetic testing, I should obtain professional genetic counseling prior to signing this form and providing my consent for the performance of the recommended testing. I understand that professional genetic counseling may better enable me to fully understand the risks and benefits of completing the recommended testing.

My signature below confirms that I understand to my satisfaction the information about the genetic testing ordered by my (or my child's) healthcare provider and that I hereby consent to participate in the testing described above.

Signature of Patient: _____ Date mm/dd/yyyy

Signature of Authorized Representative: _____

Name of Authorized Representative (if signing on behalf of Patient): _____

Relationship of Authorized Representative (if signing on behalf of Patient): _____