PATHWAY GENOMICS®

Patient Informed Consent for Genetic Testing related to Hereditary Cancer – USA and Canada

Effective Date — **November 3, 2014**

The accuracy of the genetic testing and reporting methods have been determined and verified to meet required regulatory performance standards by Pathway Genomics Corporation ("Pathway Genomics"), a licensed and CLIA (U.S. government) accredited laboratory.

I understand the following information regarding the general purpose of testing.

- Depending upon the specific genetic testing ordered by the healthcare professional on the Pathway Genomics' requisition form, I understand my specimen is being tested for my genetic makeup related: only to my inherited cancer risk; and/or my nutrigenomic effect on my inherited cancer risk. Many cancers are not inherited but occur during a person's lifetime which is why continuing regular prevention activities is important. I understand what Pathway includes in its reports is determined at Pathway's discretion.

I understand that the results from genetic testing for hereditary cancer may help a qualified healthcare professional and me learn more about my susceptibility to certain cancers and how I may reduce my cancer risk through screening and medical management. I understand that there are several types of results that can be generated, including:

- Pathogenic mutation detected - A pathogenic mutation could be identified in my genetic makeup that is associated with an increased risk of hereditary cancer. Knowing this information may help me and my healthcare professional make more informed choices about my health care, including screening and medical management based on what is known about the gene(s) in which a variant was found and the cancer associated with it.
- Likely pathogenic variant detected - A likely pathogenic variant could be identified in my genetic makeup that could be associated with an increased risk of hereditary cancer. Knowing this information may help me and my healthcare professional make more informed choices about my health care, including screening and medical management based on what is known about the gene(s) in which a variant was found and the cancer associated with it.
- No mutations detected – No mutation or variant is identified in my genetic makeup. If no one in my family, including me, has ever had cancer, I still have at least the same risk of cancer as does a person in the general population. I may still be at greater than average risk for hereditary cancer due to a genetic predisposition that cannot be detected by this test, either in the gene(s) I am tested for or in another gene linked to hereditary cancer.
- Variant of uncertain pathogenicity detected – A variant of uncertain pathogenicity could be detected. This type of change may or may not be associated with an increased risk for cancer. I understand I may have at least the same risk of cancer as the general population, and may still be at greater than average risk due to a genetic predisposition that cannot be detected by this test. As clinical or scientific information evolves, I understand that I may receive updated information about the interpretation of my results.

I understand that results from nutrigenomic testing related to cancer may help a qualified healthcare professional and me learn how my genetic makeup may affect my body's response to essential vitamins, minerals and nutrients. My healthcare professional and I may use this information to modify my diet and exercise plans to reduce my cancer risks.

I understand the general risks and limitations of genetic testing including the following:

- Blood specimens are used for testing. Side effects of having blood drawn are uncommon, but may include dizziness, fainting, soreness, pain, bleeding, bruising, and, rarely, infection.
- Genetic testing should not be used as a substitute for treating and diagnosing conditions, or the provision of health care services by a physician or other qualified healthcare professional.
- The existence of a mutation or variant does not mean I will develop cancer. The lack of mutations or variants does not mean I will not develop cancer. For some cancers, genetic causes have not been determined. The severity of the symptoms may vary from person to person.
- Genes are one of many things that may contribute to development of cancer. Other factors, such as exposures to cancer-causing substances, diet, personal and family medical history and lifestyle or behavioral choices, also contribute to risk for the development of cancer.
- Cancer can appear to "run in families", even though it may not be caused by a mutation or variant detectable by this test. This could, for example, be caused by a shared environment or lifestyle, such as tobacco use.
- Familial follow-up testing: I understand that if I have a gene mutation associated with an increased risk for cancer, my relatives can be tested to see if they have inherited the same mutation or variant as me. Pathway offers such testing (at no charge for immediate family members?).

Informed Consent Acknowledgement

I understand that this testing is voluntary and freely consent to this testing. My signature below acknowledges that:

- I understand written English sufficiently well enough, I have read and understood the front and back of this Consent, all of my questions have been answered to my satisfaction, and I agree to have the testing completed. I understand that I can receive a copy of this Consent.
- I have reached 18 years of age or older OR have the legal authority to provide this Consent and authorization for genetic testing, under all applicable laws.
- I understand Pathway Genomics may use my DNA and clinical information in medical research studies and for publication, if appropriate, unless I opt-out by initialing below. I understand that my name or other personally identifiable information will not be used in or linked by Pathway Genomics to the results of any studies and publications.

  _____ (**initial to opt-out**) I **do NOT consent** to the use of my DNA extracted from my original specimen and clinical information for anonymized medical research purposes. I understand this is deemed useful by Pathway and explained on the other side of this Consent.

_____ _____

Signature of Patient or Legally Authorized Representative Signature Date

Check one:	☐ Self	☐ Parent	☐ Legal Guardian	☐ Durable Power of Attorney for Health Care

Release of Information for Insurance Claims Processing: I understand that by requesting payment by my insurance company, Medicare or other third-party payor that I specifically authorize the release of my Protected Health Information ("PHI"), including my lab test results, to such third-party payor or its authorized agents or representatives, as necessary for the purpose of determining coverage and facilitating payment. This authorization is valid for one year. I may revoke this authorization at any time by sending a written notice to Pathway Genomics' Client Services.

I understand the general risks and limitations of testing: (continued)

- Even if a mutation or variant is present in a family, it does not mean that everyone in the family inherited this mutation or variant. The pattern of inheritance can be explained by a genetic counselor or qualified healthcare professional. Understanding this can help me and my family members prepare for varying and complicated outcomes. I understand that a genetic counselor or qualified healthcare professional can help me consider the pros and cons of speaking first with family members before being tested to find out if they want to know my results. I understand that sometimes family secrets, such as paternity, adoptions, or other difficult issues may come up.
- This testing may not provide informative results for other reasons, such as: (1) non-genetic factors; (2) individual genetic variation; (3) insufficient scientific information about the relationship between genetic information and health outcomes; (4) various laboratory and non-laboratory technical reasons; and (5) incomplete gene sequence information.
- Other risks that may be experienced as a result of this testing include: unjustified alarm and/or false reassurance that can discourage preventive measures, related emotional issues, impact on life-changing decisions, potential genetic discrimination (e.g., in employment and insurance areas) and loss of confidentiality. The testing results and information may become part of my permanent medical record and may be available to individuals and organizations with legal access to such records.

I understand that it is strongly recommended that I obtain pre-testing and post-testing counseling from someone professionally trained in cancer genetics to consider the purpose, meaning, risks, benefits, and limitations of, as well as any alternatives to, genetic testing in my particular situation, including my personal and family medical history. Counseling may be provided by a genetic counselor (such as those found on the National Society of Genetic Counseling website), advanced practice oncology nurse, doctor and other qualified healthcare professional. Pre-test counseling may help me better prepare to receive the test results and allow for advance consideration of medical options and the impact test results may have on myself and my family members. Post-test counseling provides a valuable opportunity to understand the medical interpretations of detected mutations and variants, the psychological risks and benefits of learning my genetic test results, how families inherit cancers and the risk of passing an inherited variant on to my children, options for additional independent testing, and the importance of continuing regular cancer surveillance and prevention activities, among other things.

I understand that if testing results are inconclusive that I may be asked for an additional specimen(s). This Consent is effective for any such additional specimen(s).

If a minor will be tested, I understand the following: While genetic report information may be similar for adults and minors, the consequences of genetic testing of minors are relatively new and less understood. The National Society of Genetic Counselors recommends that the social and psychological risks and benefits of early identification of genetic issues from the perspective of the minor and parent/guardian be carefully considered and include genetic counseling when discussing genetic testing of children for inherited cancer risk. .

I understand the following information about confidentiality and disclosure of my personal information:

- My personal information and test results are confidential. While there can be no guarantee of privacy, Pathway Genomics has established reasonable safeguards to protect it. This information and the test results will be released to the ordering healthcare professional. I may request a copy of my lab results from Pathway Genomics' Client Services (see "Questions" below for contact information). For more information about my rights and Pathway Genomics' privacy practices, see Notice of Privacy Practices available on www.pathway.com.
- This information and the results may also be disclosed if required by law, such as in response to a subpoena.
- I understand that if I share this information or these test results with anyone, I am responsible for any compromise of confidentiality that may result from such sharing.
- The original specimen(s) may be securely stored for sixty (60) days from the date of collection and any remaining isolated DNA may be securely stored in accordance with applicable laws, regulations and standards. After such storage, the specimen(s) and the isolated DNA will be properly destroyed in accordance with applicable laws and regulations and the testing laboratory's standard operating procedures.

I understand the following regarding specimens for Medical Research Purposes: I authorize that my DNA extracted from my original specimen may be retained up to 10 years by Pathway Genomics as deemed useful for medical research purposes to develop new genetic tests. I understand that to protect my identity: a unique identifier will be assigned to my specimen; all resulting research data will be recorded, handled and stored using this unique identifier; my name will be unavailable to any member of the research team; and my identity will not be released or disclosed to others outside of Pathway Genomics. No compensation will be given me nor will I be owed any funds due to any inventions(s) resulting from research and development using my specimen(s). I may refuse to submit my specimen for use in this way and this will not affect my results. Unless I indicate on the front that I do not consent to anonymous medical research, I understand that my specimen(s) may be used in this manner.

I understand I may withdraw my consent: Under CLIA regulations, Pathway Genomics cannot destroy medical records. However at my written request and according to my instructions, Pathway Genomics can: a) destroy my DNA specimen(s) at the next regularly scheduled destruction cycle; b) delete my account; and c) move all medical information, including results report(s), into a into a secure, offline storage area with limited access. This means my account and results report(s) will not be searchable in Pathway Genomics systems by regular means and I and my healthcare professional will not be able to obtain a copy of my account information and results report(s) from Pathway Genomics. A request to withdraw my consent may be made to Pathway Genomics' Client Services (see phone number under "Questions" below).

California residents only: I understand I have a right to receive a copy of the Experimental Subject's Bill of Rights from my ordering healthcare professional.

Questions: If I have further questions about this testing, I understand that I can either contact a genetic counselor, other qualified healthcare professional or Pathway Genomics' Client Services at 1-877-505-7374, 8:00 AM to 5:00 PM Pacific Time, Monday through Friday to speak to a Pathway Genetic Counselor.

