Patient Informed Consent for CancerIntercept™ Monitor

PATHWAY GENOMICS®

Effective Date — **September 10, 2015**

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 and benefits of testing:

- The purpose of this genetic test is to identify somatic cancer derived mutations at 96 hotspots in nine cancer driver genes involved primarily in breast, ovarian, lung, and colorectal cancers and melanoma. The test method used for detecting these somatic mutations is known as a liquid biopsy. Identification of any of the 96 somatic mutations could potentially help personalize my oncology treatment by providing tumor profiling, monitor disease progression and tumor evolution, and provide options for treatment.

I understand the following information regarding CancerIntercept™ Monitor results:

- The CancerIntercept™ Monitor test uses a proprietary method for isolating circulating tumor DNA (ctDNA) in blood. This ctDNA is analyzed for 96 somatic mutations in nine genes commonly mutated in tumor tissue of patients with specific types of cancer. Identification of a mutation could have implications for my healthcare management and cancer surveillance or treatment.
- A positive result indicates one or more of the 96 somatic mutations was identified. Identification of a mutation in my specimen will have different implications for treatment depending on the variant detected, my diagnosis, and the stage of disease I am in (just diagnosed, in the middle of treatment, or in remission). This screening test is not designed to diagnose cancer. Additional testing, including imaging studies, may be required as a follow up to a positive result. Recommendations about follow up testing will be made by my oncologist or my primary healthcare provider.
- A negative result indicates none of the 96 somatic mutations analyzed were identified in my specimen. A negative result does not mean that I do not currently have a tumor. This result only indicates that tumor DNA associated with one of the 96 mutations analyzed was not detected. Other tumors that are not associated with the mutations analyzed are not detected by this test.
- Knowing this information may help me and my healthcare provider make informed choices about my health care, including additional screening tests and medical management based on what is known about the mutations identified and the type of cancer associated with them. I understand that clinical trial matching may be available if my physician requests it.
- Pathway Genomics may contact me for additional information or follow-up clinical history at any point after I undergo this testing.

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

- Two tubes of blood (10 mL each) will be collected to perform the liquid biopsy. Risks 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 for the provision of health care services by a physician or other qualified healthcare professional.
- The lack of detection of any mutations does not mean that I definitively do not have a cancer tumor currently, nor does it mean that I will not develop cancer at a later time. The CancerIntercept™ Monitor test only analyzes mutations associated with some common tumor types. There may be tumors of the types usually associated with these 96 mutations that have not developed the specific mutations tested which will be missed as well as tumors that are not yet shedding DNA into the blood stream that cannot be detected. Other tumors not associated with the 96 somatic mutations analyzed will not be identified by this test.
- This test 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.
- This test does not test for hereditary cancer syndromes. The test is designed to detect only somatic mutations in ctDNA.
- 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, 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.

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
- I have read and understood the front and back of this consent, all of my questions have been asked and answered to my satisfaction, and I agree to this testing. I understand that I can receive a copy of this consent by calling Client Services. (See "Questions").
- I am 18 years of age or older and 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, except if I am a New York resident where an opt-in is required for this. 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 extracted DNA sample and clinical information for anonymous medical research purposes. I understand this is deemed useful by Pathway Genomics and explained on the other side of this Consent.

_____ (**initial to opt-in**) **NEW YORK Residents:** My DNA, extracted from my original specimen, and my clinical information can be retained for greater than 60 days and up to ten (10) years after the completion of testing for anonymized medical research purposes as described above.

_____ _____

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 that it is strongly recommended that I obtain pre-testing and post-testing counseling from someone professionally trained in cancer genetics or oncology to consider the purpose, meaning, risks, benefits, and limitations of, as well as any alternatives to, genetic testing in my particular situation, including medical issues based on my personal medical history. Counseling may be provided by an advanced practice oncology nurse, doctor, or 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 me and my health. Post-test counseling provides a valuable opportunity to understand the medical interpretations of detected mutations, the psychological risks and benefits of learning my genetic test results, options for additional independent testing, and the importance of continuing 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).

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.
- If I have opted out of allowing storage of my sample for research, 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 understand that if I am not a resident of New York, unless I opt-out, as checked above, that I am authorizing 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 if I am a resident of New York, I may opt-in for this retention of my original specimen for up to 10 years by checking the correct box above. I understand that to protect my identity: a unique identifier will be assigned to my specimen and 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 invention(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 in the front page 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).

I understand that if I am requesting my test online, I will be provided an ordering healthcare professional through a national physician network ('physician network") to offer telehealth services as may be defined by state law.

- When using telehealth, my health information may be transmitted through electronic communication to allow a physician at a different location to receive my medical information. I understand that there are risks and benefits in utilizing telehealth services. Such risks include: insufficiency of information transmitted; delays in evaluation and treatment; security and privacy compromise; and/or incomplete medical records. However, the physician network has implemented certain industry measures in an effort to mitigate such risks. There are also benefits to providing services through telehealth: the improvement of access to health services and an expedient, efficient and cost-effective way of providing testing to me. The physician network has licensed physicians trained in telehealth. If this testing is authorized by a physician who is a member of this network, then my signature below indicates that I acknowledge and confirm that the following will apply:
  - I have been informed about the testing and its delivery through telehealth means.
  - I consent to the use of telehealth services in the course of the requested testing. If I do not consent to the use of telehealth services, I will not request the test.
  - I understand that privacy and the confidentiality laws apply to telehealth services, and that disclosure of my information is protected as disclosed under this Consent.
  - I understand a variety of alternative care methods are available me, and these alternatives have been explained.
  - I understand it is my duty to inform my healthcare professional of electronic interactions regarding my care.
  - I understand that the anticipated benefits from the use of telehealth services is not guaranteed or assured.

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. I may also call this number to set up an appointment to speak with a Pathway Genomics genetic counselor.