

Patient Informed Consent for Genetic Testing – Nutrigenetic and New York Only

Effective Date — **November 6, 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, meaning and benefits of testing.

- I understand my specimen is being tested for genetic variations. Depending upon the specific genetic testing ordered by the healthcare professional on the testing Pathway Genomics’ requisition form, the results of this testing can provide information that may help my healthcare professional and me learn more about how my genes affect health factors and conditions, and diet, nutrition, and/or exercise.
- The information that can be learned from this testing may help me work with a healthcare professional to make changes to my medical care or health maintenance. I understand that I should not make any such changes without consulting a qualified healthcare professional.

I understand the general risks and limitations of testing:

- 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 healthcare professional.
- *Genes are one of many things that may contribute to health outcomes and development of certain medical conditions.* Many other factors, such as environmental factors, diet, personal and family medical history and lifestyle choices, also contribute to health status and outcomes.
- 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; and (4) various laboratory and non-laboratory technical reasons.
- Saliva or blood specimens may be used for testing. Side effects of having blood drawn are uncommon, but may include dizziness, fainting, soreness, pain, bleeding, bruising, and, rarely, infection.
- Other risks that may be experienced as a result of this testing include: 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 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 I may discuss alternatives to undergoing genetic testing, such as regular laboratory testing and physical examination, with a healthcare professional or a genetic counselor.

I understand the importance of discussing the purpose, meaning, benefits, risks and limitations of this testing, as well as any alternatives, with a genetic counselor or other qualified healthcare professional and of having my pre-testing questions answered.

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 adult-onset disorders.

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, have read and understood the front and back of this Consent, all of my questions have been answered to my satisfaction, and agree to have the testing completed. I understand that I can receive a copy of this Consent.
- If using a Medivo ordering physician (see back), I have reached 18 years of age or older AND I have the legal authority to provide this Consent and authorization for genetic testing, under all applicable laws.
- If using a non-Medivo ordering healthcare professional, I have reached 18 years of age or older AND/OR otherwise 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-in**) **NEW YORK Residents:** My DNA extracted from my original specimen can be retained for greater than 60 days and up to ten (10) years after the completion of testing for anonymized medical research purposes.

Signature of Patient or Legally Authorized Representative

Signature Date

Check one:	<input type="checkbox"/> Self	<input type="checkbox"/> Parent	<input type="checkbox"/> Legal Guardian	<input type="checkbox"/> Durable Power of Attorney for Health Care
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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 understand that I may revoke this authorization at any time by sending a written notice to Pathway Genomics’ Client Services.

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: By initialing on the front of this Consent above the signature line, I can authorize that my DNA extracted from my original specimen 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.

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 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 your 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 do not have an ordering healthcare professional, the testing laboratory may use a Medivo member physician to offer telehealth services for FIT testing only.

- 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, Medivo 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. Medivo is a national network of licensed physicians trained in telehealth. If this testing is authorized by a Medivo member physician, 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 to speak to a Pathway Genetic Counselor.

Conditions Description for Pathway Fit® Report

The Patient's report includes genetic information, genetic tendencies, and recommendations for each of the following conditions:

1. General – Genetic predispositions possibly affecting diet, nutritional needs, and exercise.
2. Diet – Genetic predispositions possibly affecting responses to certain foods and types of fats with dietary recommendations.
3. Eating Behavior Traits – Genetic predispositions possibly affecting snacking, hunger, feeling of fullness, overeating, desire for food, and desire for sweets.
4. Food Reactions – Genetic predispositions possibly affecting bitter taste, sweet taste, caffeine metabolism, lactose intolerance, and alcohol flush.
5. Nutritional Needs – Genetic predispositions possibly affecting my levels of essential nutrients, including vitamins A, B-2, B-6, B-12, C, D, E, Omega-3, Omega-6, and folic acid.
6. Exercise – Genetic predispositions possibly affecting potential benefits from endurance and possible effects of exercise on weight loss, blood pressure, cholesterol levels, body fat and insulin sensitivity, and aerobic capacity (VO2 max).
7. Body and Weight – Genetic predispositions possibly affecting control of obesity, weight loss and regain, and metabolism.