Test Requisition Form COMPLETE ENTIRE FORM TO AVOID DELAYS

PATHWAY GENOMICS®

ACCESSION NO. (LAB USE ONLY)

SPECIMEN ID

PLACE BARCODE HERE

PATIENT INFORMATION

NAME (LAST, FIRST, MI)			DOB (MM/DD/YY)	GENDER ☐ MALE ☐ FEMALE
PRIMARY ETHNICITY (CHOOSE ONE) ☐ AFRICAN ☐ ASIAN ☐ CAUCASIAN ☐ HISPANIC	EMAIL		HEIGHT	WEIGHT
PHONE	ADDRESS	CITY	STATE	ZIP

ORDER AUTHORIZED BY

PHYSICIAN NAME		MEDICAL CREDENTIALS	NPI #
PHONE	FAX	EMAIL	
FACILITY NAME	ADDRESS	CITY	STATE ZIP

SPECIMEN INFORMATION (REQUIRED)

DATE OF COLLECTION	TIME OF COLLECTION

SPECIMEN TYPE
☐ SALIVA ☐ BUCCAL SWAB
☐ BLOOD (LAVENDER CAP)
☐ BLOOD (STRECK CELL-FREE DNA BCT)

FOR INSURANCE BILLING ONLY: ICD-10 CODES (REQUIRED) WITH CORRESPONDING CHART NOTES

ICD-10 CODES

GENERAL HEALTH AND WELLNESS

☐ PATHWAY FIT® (1503)
DIET GUIDELINES (CHOOSE ONE) ☐ STANDARD ☐ GLUTEN-FREE ☐ VEGETARIAN ☐ DAIRY-FREE

☐ HEALTHY WEIGHT DNA INSIGHT® (1534)
DIET GUIDELINES (CHOOSE ONE) ☐ STANDARD ☐ GLUTEN-FREE ☐ VEGETARIAN ☐ DAIRY-FREE

☐ HEALTHY WOMAN DNA INSIGHT® (1525)
DIET GUIDELINES (CHOOSE ONE) ☐ STANDARD ☐ GLUTEN-FREE ☐ VEGETARIAN ☐ DAIRY-FREE ☐ PREGNANCY AND LACTATION

☐ SKINFIT™ (2001)

☐ CARDIAC HEALTHY WEIGHT DNA INSIGHT® (1688)
DIET GUIDELINES (CHOOSE ONE) ☐ STANDARD ☐ GLUTEN-FREE ☐ VEGETARIAN ☐ DAIRY-FREE

PHARMACOGENOMICS

☐ MENTAL HEALTH DNA INSIGHT® (1469)

☐ CARDIAC DNA INSIGHT® (1710)

☐ PAIN MEDICATION DNA INSIGHT® (1275)

CARRIER SCREENING

☐ CARRIER STATUS DNA INSIGHT® (1682)

HEREDITARY CANCER * MUST BE AUTHORIZED TO ORDER AND MUST HAVE SUPPORTING CLINICAL HISTORY FORMS FILLED OUT TO COMPLETION

☐ BRCATRUE® (1829)

☐ BRCATRUE® ASHKENAZI JEWISH (3-SITE) (1839)

☐ BRCATRUE® ASHKENAZI JEWISH WITH REFLEX TO BRCATRUE® (1845)

☐ BRCATRUE® ASHKENAZI JEWISH (3-SITE) WITH REFLEX TO BREASTRUE® HIGH RISK PANEL (1847)

☐ BREASTTRUE® HIGH RISK PANEL® (1849)

☐ BRCATRUE® HISPANIC (8-SITE) (1861)

☐ BRCATRUE® HISPANIC (8-SITE) WITH REFLEX TO BRCATRUE® (1865)

☐ BRCATRUE® HISPANIC (8-SITE) WITH REFLEX TO BREASTTRUE® HIGH RISK PANEL (1863)

☐ BRCATRUE® WITH REFLEX TO BREASTTRUE® HIGH RISK PANEL (1855)

☐ COLOTRUE® (1942)

☐ LYNCHSYNDROMETRUE® (1420)

☐ LYNCHSYNDROMETRUE® WITH REFLEX TO COLOTRUE® (1423)

SINGLE SITE (MUST ATTACH A COPY OF ORIGINAL TEST RESULT WITH VARIANT REQUESTED)

☐ SINGLE SITE ANALYSIS - SPECIFY GENE	SPECIFY VARIANT (HGVS NOMENCLATURE)	RELATIONSHIP TO PATIENT CARRYING VARIANT

LIQUID BIOPSY * MUST BE AUTHORIZED TO ORDER AND MUST HAVE SUPPORTING CLINICAL HISTORY FORMS FILLED OUT TO COMPLETION

☐ CANCERINTERCEPT™ DETECT (3101)

☐ CANCERINTERCEPT™ MONITOR (3102)

☐ CANCERINTERCEPT™ MONITOR + CLINICAL TRIAL MATCHING (3103)

PAYMENT OPTIONS (SIGNATURE REQUIRED)

☐ PATIENT PAY	☐ BILL INSURANCE (attach front and back copy of insurance card)	FIRST AND LAST NAME OF FINANCIALLY RESPONSIBLE PARTY IF NOT PATIENT (eg. patient is minor)
☐ INVOICE PRACTICE	INSURANCE COMPANY NAME	POLICY NUMBER/MEMBER ID

Patient Acknowledgment and Authorization for Insurance Billing and Report Release: If I have provided my insurance information for direct insurance/3rd party billing: **I hereby authorize my insurance benefits to be paid directly to Pathway Genomics Corporation (Pathway) and authorize Pathway to release medical information concerning my testing, including upon request my genetic testing results, to my insurer and any business associate of insurer (TPB, TPA, etc.).** I authorize Pathway to be my Designated Representative for purposes of appealing any denial of health benefits. I understand that I am responsible for any amounts Pathway bills directly to me, including amounts that my insurer determines are my responsibility after calculating deductibles, co-payments and co-insurance due under my policy. I understand that I am legally responsible for sending Pathway any money received from my health insurance company for performance of this genetic test.

▶ Patient Signature:_____ Date:_____

ORDERING HEALTHCARE PROFESSIONAL (SIGNATURE REQUIRED)

Informed Consent and Statement of Medical Necessity: I hereby confirm that the test(s) are medically necessary for the treatment and/or plan of care for the patient. I further hereby confirm that the information has been supplied about genetic testing and that an appropriate Pathway informed consent has been signed by the patient and is on file with the ordering healthcare professional.

Did patient opt-out for the use of their sample for research purposes in the consent? ☐ Yes ☐ No ▶ Physician Signature:_____ Date:_____

PATHWAYFIT®

ICD-10 Code	Description
E56.9	Vitamin deficiency, unspecified
E78.0	Pure hypercholesterolemia
E78.1	Pure hyperglyceridemia
E78.2	Mixed hyperlipidemia
E78.5	Hyperlipidemia, unspecified
E78.4	Other hyperlipidemia
E88.89	Other specified metabolic disorders
E78.89	Other lipoprotein metabolism disorders
E78.81	Lipoid dermatoarthritis
E88.9	Metabolic disorder, unspecified
E80.3	Defects of catalase and peroxidase
C96.6	Unifocal Langerhans-cell histiocytosis
C96.5	Multifocal and unisystemic Langerhans-cell histiocytosis

HEALTHY WOMAN DNA INSIGHT®

Z68.26	Body mass index (BMI) 26.0-26.9, adult
E66.3	Overweight

HEALTHY WEIGHT DNA INSIGHT®

R63.5	Abnormal weight gain
F41.9	Anxiety disorder, unspecified
E78.2	Mixed hyperlipidemia
E66.9	Obesity, unspecified
F43.0	Acute stress reaction
E53.8	Deficiency of other specified B group vitamins
R53.83	Other fatigue
R53.81	Other malaise
E66.3	Overweight
K21.0	Gastro-esophageal reflux disease with esophagitis
N91.5	Oligomenorrhea, unspecified
E55.9	Vitamin D deficiency, unspecified

CARDIAC HEALTHY WEIGHT DNA INSIGHT®

Z71.3	Dietary counseling and surveillance
R03.0	Elevated blood-pressure reading, without diagnosis of hypertension
K21.9	Gastro-esophageal reflux disease without esophagitis
N95.1	Menopausal and female climacteric states
Z83.3	Family history of diabetes mellitus
R94.5	Abnormal results of liver function studies
E66.9	Obesity, unspecified
R53.83	Other fatigue
E29.1	Testicular hypofunction
E66.3	Overweight
E06.9	Thyroiditis, unspecified
E23.7	Disorder of pituitary gland, unspecified
E23.3	Hypothalamic dysfunction, not elsewhere classified
I10	Essential (primary) hypertension

MENTAL HEALTH DNA INSIGHT®

Z00.00	Encounter for general adult medical examination without abnormal findings
T50.995A	Adverse effect of other drugs, medicaments and biological substances, initial encounter
T50.7X5A	Adverse effect of analeptics and opioid receptor antagonists, initial encounter

CARDIAC DNA INSIGHT®

R10.13	Epigastric pain
R10.9	Unspecified abdominal pain
D68.311	Acquired hemophilia
I48.91	Unspecified atrial fibrillation
I10	Essential (primary) hypertension
Z68.34	Body mass index (BMI) 34.0-34.9, adult
K59.00	Constipation, unspecified
E11.9	Type 2 diabetes mellitus without complications
Z84.81	Family history of carrier of genetic disease
Z82.49	Family history of ischemic heart disease and other diseases of the circulatory system
M72.9	Fibroblastic disorder, unspecified
Z15.89	Genetic susceptibility to other disease
I20.0	Unstable angina
Z79.899	Other long term (current) drug therapy
E78.2	Mixed hyperlipidemia
M79.7	Fibromyalgia
E66.9	Obesity, unspecified
I20.9	Angina pectoris, unspecified
E78.5	Hyperlipidemia, unspecified
K59.09	Other constipation
T50.995A	Adverse effect of other drugs, medicaments and biological substances, initial encounter
R53.1	Weakness
G93.3	Postviral fatigue syndrome
R53.83	Other fatigue
R53.81	Other malaise
E66.3	Overweight
M25.50	Pain in unspecified joint
I73.9	Peripheral vascular disease, unspecified
I80.209	Phlebitis and thrombophlebitis of unspecified deep vessels of unspecified lower extremity
Z13.220	Encounter for screening for lipoid disorders
E03.9	Hypothyroidism, unspecified
T50.7X5A	Adverse effect of analeptics and opioid receptor antagonists, initial encounter
E88.9	Metabolic disorder, unspecified
E63.9	Nutritional deficiency, unspecified
E55.9	Vitamin D deficiency, unspecified

PAIN MEDICATION DNA INSIGHT®

G89.4	Chronic pain syndrome
G89.29	Other chronic pain
T50.995A	Adverse effect of other drugs, medicaments and biological substances, initial encounter
T50.7X5A	Adverse effect of analeptics and opioid receptor antagonists, initial encounter
Z79.1	Long term (current) use of non-steroidal anti-inflammatories (NSAID)
Z79.899	Other long term (current) drug therapy

CARRIER STATUS DNA INSIGHT®	
Z84.81	Family history of carrier of genetic disease
N46.9	Male infertility, unspecified
N97.9	Female infertility, unspecified
O35.2XX0	Maternal care for (suspected) hereditary disease in fetus, not applicable or unspecified
Z13.71	Encounter for nonprocreative screening for genetic disease carrier status
Z13.89	Encounter for screening for other disorder

BREAST CANCER - HEREDITARY CANCER TESTS	
C50.019	Malignant neoplasm of nipple and areola, unspecified female breast
C50.119	Malignant neoplasm of central portion of unspecified female breast
C50.219	Malignant neoplasm of upper-inner quadrant of unspecified female breast
C50.319	Malignant neoplasm of lower-inner quadrant of unspecified female breast
C50.419	Malignant neoplasm of upper-outer quadrant of unspecified female breast
C50.519	Malignant neoplasm of lower-outer quadrant of unspecified female breast
C50.619	Malignant neoplasm of axillary tail of unspecified female breast
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast
C50.919	Malignant neoplasm of unspecified site of unspecified female breast
C50.029	Malignant neoplasm of nipple and areola, unspecified male breast
C50.929	Malignant neoplasm of unspecified site of unspecified male breast
D05.90	Unspecified type of carcinoma in situ of unspecified breast
Z85.3	Personal history of malignant neoplasm of breast
Z80.3	Family history of malignant neoplasm of breast
Z80.8	Family history of malignant neoplasm of other organs or systems
Z84.81	Family history of carrier of genetic disease

OVARIAN CANCER - HEREDITARY CANCER TESTS	
C56.9	Malignant neoplasm of unspecified ovary
C79.60	Secondary malignant neoplasm of unspecified ovary
D07.39	Carcinoma in situ of other female genital organs
N95.1	Menopausal and female climacteric states
Z85.43	Personal history of malignant neoplasm of ovary
Z80.41	Family history of malignant neoplasm of ovary

UTERINE CANCER - HEREDITARY CANCER TESTS	
C55	Malignant neoplasm of uterus, part unspecified
C54.9	Malignant neoplasm of corpus uteri, unspecified
Z80.8	Family history of malignant neoplasm of other organs or systems

PROSTATE CANCER - HEREDITARY CANCER TESTS	
C61	Malignant neoplasm of prostate
Z85.46	Personal history of malignant neoplasm of prostate
Z80.42	Family history of malignant neoplasm of prostate

SINGLE-SITE GENETIC TESTING - HEREDITARY CANCER TESTS	
Z84.81	Family history of carrier of genetic disease

COLORECTAL CANCER - HEREDITARY CANCER TESTS	
C18.3	Malignant neoplasm of hepatic flexure
C18.4	Malignant neoplasm of transverse colon
C18.6	Malignant neoplasm of descending colon
C18.7	Malignant neoplasm of sigmoid colon
C18.0	Malignant neoplasm of cecum
C18.1	Malignant neoplasm of appendix
C18.2	Malignant neoplasm of ascending colon
C18.5	Malignant neoplasm of splenic flexure
C18.8	Malignant neoplasm of overlapping sites of colon
C18.9	Malignant neoplasm of colon, unspecified
C20	Malignant neoplasm of rectum
D12.6	Benign neoplasm of colon, unspecified
Z85.038	Personal history of other malignant neoplasm of large intestine
Z86.010	Personal history of colonic polyps
Z80.0	Family history of malignant neoplasm of digestive organs

PANCREATIC CANCER - HEREDITARY CANCER TESTS	
C25.0	Malignant neoplasm of head of pancreas
C25.1	Malignant neoplasm of body of pancreas
C25.2	Malignant neoplasm of tail of pancreas
C25.3	Malignant neoplasm of pancreatic duct
C25.4	Malignant neoplasm of endocrine pancreas
C25.7	Malignant neoplasm of other parts of pancreas
C25.9	Malignant neoplasm of pancreas, unspecified
Z80.0	Family history of malignant neoplasm of digestive organs

OTHER CANCER SITES - HEREDITARY CANCER TESTS	
C16.9	Malignant neoplasm of stomach, unspecified
C17.9	Malignant neoplasm of small intestine, unspecified
C49.9	Malignant neoplasm of connective and soft tissue, unspecified
C67.9	Malignant neoplasm of bladder, unspecified
C64.9	Malignant neoplasm of unspecified kidney, except renal pelvis
C65.9	Malignant neoplasm of unspecified renal pelvis
C66.9	Malignant neoplasm of unspecified ureter
C71.0	Malignant neoplasm of cerebrum, except lobes and ventricles
C73	Malignant neoplasm of thyroid gland
E03.9	Hypothyroidism, unspecified
Z80.0	Family history of malignant neoplasm of digestive organs
Z80.8	Family history of malignant neoplasm of other organs or systems

MELANOMA - HEREDITARY CANCER TESTS	
C43.0	Malignant melanoma of lip
C43.10	Malignant melanoma of unspecified eyelid, including canthus
C43.20	Malignant melanoma of unspecified ear and external auricular canal
C43.39	Malignant melanoma of other parts of face
D03.4	Melanoma in situ of scalp and neck
C43.59	Malignant melanoma of other part of trunk
C43.60	Malignant melanoma of unspecified upper limb, including shoulder
C43.70	Malignant melanoma of unspecified lower limb, including hip
C43.8	Malignant melanoma of overlapping sites of skin
C43.9	Malignant melanoma of skin, unspecified
Z80.8	Family history of malignant neoplasm of other organs or systems

NO DIAGNOSIS OF CANCER - CANCERINTERCEPT™ DETECT	
Z12.9	Encounter for screening for malignant neoplasm, site unspecified

BREAST CANCER - CANCERINTERCEPT™ MONITOR TEST	
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast
C50.919	Malignant neoplasm of unspecified site of unspecified female breast
D05.90	Unspecified type of carcinoma in situ of unspecified breast
D05.90 and Z17.0	Unspecified type of carcinoma in situ of unspecified breast with Estrogen receptor positive status [ER+]
D05.90 and Z17.1	Unspecified type of carcinoma in situ of unspecified breast with Estrogen receptor negative status [ER-]
Z85.3	Personal history of malignant neoplasm of breast

COLORECTAL CANCER - CANCERINTERCEPT™ MONITOR TEST	
C18.9	Malignant neoplasm of colon, unspecified
C20.0	Malignant neoplasm of rectum
C21.0	Malignant neoplasm of anus, unspecified
D01.0	Carcinoma in situ of colon
D01.2	Carcinoma in situ of rectum
Z85.038	Personal history of other malignant neoplasm of large intestine

LUNG CANCER - CANCERINTERCEPT™ MONITOR TEST	
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C49.9	Malignant neoplasm of connective and soft tissue, unspecified
C7A.090	Malignant carcinoid tumor of the bronchus and lung

MELANOMA - CANCERINTERCEPT™ MONITOR TEST	
D03.9	Melanoma in situ, unspecified
C4A.9	Merkel cell carcinoma, unspecified
Z85.820	Personal history of malignant melanoma of skin

OVARIAN CANCER - CANCERINTERCEPT™ MONITOR TEST	
C56.9	Malignant neoplasm of unspecified ovary
Z85.40	Personal history of malignant neoplasm of unspecified female genital organ
Z85.43	Personal history of malignant neoplasm of ovary

PANCREATIC CANCER - CANCERINTERCEPT™ MONITOR TEST	
C25.0	Malignant neoplasm of head of pancreas
C25.3	Malignant neoplasm of pancreatic duct
C25.4	Malignant neoplasm of endocrine pancreas
C25.9	Malignant neoplasm of pancreas, unspecified

PROSTATE CANCER - CANCERINTERCEPT™ MONITOR TEST	
C61	Malignant neoplasm of prostate
Z85.46	Personal history of malignant neoplasm of prostate

HEAD AND NECK CANCER - CANCERINTERCEPT™ MONITOR TEST	
C49.0	Malignant neoplasm of connective and soft tissue of head, face and neck
C76.0	Malignant neoplasm of head, face and neck

THYROID CANCER - CANCERINTERCEPT™ MONITOR TEST	
Z85.850	Personal history of malignant neoplasm of thyroid
C73	Malignant neoplasm of thyroid gland

OTHER CANCERS AND DIAGNOSES - CANCERINTERCEPT™ MONITOR TEST	
C16.9	Malignant neoplasm of stomach, unspecified
C17.9	Malignant neoplasm of small intestine, unspecified
C54.9	Malignant neoplasm of corpus uteri, unspecified
C64.9	Malignant neoplasm of unspecified kidney, except renal pelvis
C79.89	Secondary malignant neoplasm of other specified sites
C80.0	Disseminated malignant neoplasm, unspecified
C80.1	Malignant (primary) neoplasm, unspecified
D48.1	Neoplasm of uncertain behavior of connective and other soft tissue
D49.5	Neoplasm of unspecified behavior of other genitourinary organs
C54.9	Malignant neoplasm of corpus uteri, unspecified
C54.9, C54.0, C54.8	Malignant neoplasm of corpus uteri, unspecified; Malignant neoplasm of isthmus uteri; Malignant neoplasm of overlapping sites of corpus uteri
Z85.00	Personal history of malignant neoplasm of unspecified digestive organ
Z85.028	Personal history of other malignant neoplasm of stomach
Z85.05	Personal history of malignant neoplasm of liver
Z85.41	Personal history of malignant neoplasm of cervix uteri
Z85.42	Personal history of malignant neoplasm of other parts of uterus
Z85.47	Personal history of malignant neoplasm of testis
Z85.51	Personal history of malignant neoplasm of bladder
Z85.528	Personal history of other malignant neoplasm of kidney
Z85.9	Personal history of malignant neoplasm, unspecified

Clinical History Questionnaire

PATHWAY GENOMICS®

Patient Name: _____ **Date of Birth:** _____

Have you ever been diagnosed with cancer? ☐ Yes ☐ No **Purpose for testing:** _____

Are you of Ashkenazi Jewish decent? ☐ Yes ☐ No **Ethnicity:** ☐ African ☐ Asian ☐ Caucasian ☐ Hispanic ☐ Other

Family History | Do you have any family members who have been diagnosed with cancer? ☐ Yes ☐ No

Maternal	Paternal	Relationship	First/Second Degree	Cancer or Polyp History	Previous Genetic Testing (Positive/Negative)	Age at diagnosis
☐	☑	(Example) Female Cousin	First Degree	Colon cancer	Lynch Testing - Negative	62
☐	☐	Mother				
☐	☐	Father				
☐	☐					
☐	☐					
☐	☐					
☐	☐					

Previous Genetic Testing | ☐ Yes (please attach results) ☐ No

☐ Hereditary Breast and Ovarian Cancer gene testing (BRCA1/2 gene testing) Result: _____

☐ Lynch Syndrome gene testing (MLH1, MSH2, MSH6, PMS2, EPCAM) Result: _____

☐ Other hereditary cancer testing: Gene: _____ Result: _____

Patient History (personal history of cancer) | If you have not been diagnosed with cancer stop here

Personal History Of:	Age At Diagnosis	Details
☐ Breast Cancer		
☐ Ovarian Cancer		
☐ Colon Cancer		
☐ Polyps		
☐ Pancreatic Cancer		
☐ Prostate Cancer		
☐ Melanoma		
☐ Endometrial Cancer		
☐ Other Cancer		

Personal History Of:	Date of Procedure	Details
☐ Bone Marrow Transplant		
☐ Stem Cell Transplant		
☐ Blood Transfusion		
☐ Other Transfusion		

PATHWAY GENOMICS®

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

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 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:

- Saliva or 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.

