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)	PRIMARY ETHNICITY (CHOOSE ONE) ☐ AFRICAN ☐ ASIAN ☐ CAUCASIAN ☐ HISPANIC	DOB (MM/DD/YY)	GENDER ☐ MALE ☐ FEMALE
ADDRESS (STREET, CITY, STATE, ZIP)		HEIGHT (IN)	WEIGHT (LB)
PHONE	EMAIL	MEDICATIONS	

ORDER AUTHORIZED BY

PHYSICIAN NAME	MEDICAL CREDENTIALS	NPI #
ADDRESS (STREET, CITY, STATE, ZIP)		
FACILITY NAME	PHONE	FAX

SPECIMEN INFORMATION (REQUIRED)

DATE OF COLLECTION	TIME OF COLLECTION
SPECIMEN TYPE ☐ SALIVA ☐ BUCCAL SWAB ☐ BLOOD (LAVENDER CAP) ☐ BLOOD (STRECK CELL-FREE DNA BCT)	
EMAIL (IF APPLICABLE)	

GENERAL HEALTH AND WELLNESS

☐ * PATHWAY FIT® (1503)	☐ HEALTHY WEIGHT DNA INSIGHT® (1534)	☐ * HEALTHY WOMAN DNA INSIGHT® (1525)	☐ * CARDIAC HEALTHY WEIGHT DNA INSIGHT® (1688)
☐ SKINFIT™ (2001)			

*** INCLUDES ONE DIET GUIDELINES REPORT AT NO ADDITIONAL COST:**
DIET GUIDELINES (CHOOSE ONE) ☐ STANDARD (1728) ☐ GLUTEN-FREE (1652) ☐ VEGETARIAN (1729) ☐ DAIRY-FREE (1730) ☐ PREGNANCY AND LACTATION (1363)

PHARMACOGENOMICS

☐ MENTAL HEALTH DNA INSIGHT® (1469)	☐ CARDIAC DNA INSIGHT® (1710)	☐ PAIN MEDICATION DNA INSIGHT® (1275)	☐ CARRIER STATUS DNA INSIGHT® (1682)

CARRIER SCREENING

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

☐ BRCATRUE® (1829)	☐ BREASTTRUE® HIGH RISK PANEL® (1849)	☐ BRCATRUE® WITH REFLEX TO BREASTTRUE® HIGH RISK PANEL (1855)	☐ COLOTRUE® (1942)

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 PROVIDE ICD-10 CODE AND ATTACH CLINICAL HISTORY FORMS

☐ CANCERINTERCEPT™ DETECT (3101)	☐ CANCERINTERCEPT™ MONITOR (3102)	☐ CANCERINTERCEPT™ MONITOR + CLINICAL TRIAL MATCHING (3103)	ICD-10 CODE FOR CANCERINTERCEPT™

PAYMENT OPTIONS (SIGNATURE REQUIRED)

☐ PATIENT PAY	☐ BILL INSURANCE (ATTACH FRONT AND BACK COPY OF INSURANCE CARD, CHART NOTES)	FIRST AND LAST NAME OF FINANCIALLY RESPONSIBLE PARTY IF NOT PATIENT (EG. PATIENT IS MINOR)	
☐ INVOICE PRACTICE	INSURANCE COMPANY NAME	POLICY NUMBER/MEMBER ID	ICD-10 CODES FOR INSURANCE

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

CANCERINTERCEPT™ MONITOR

Clinical History Questionnaire

PATHWAY GENOMICS®

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

PERSONAL HISTORY: ☐ No personal history of cancer

If you have no personal history of cancer, **STOP** and fill out the CancerIntercept™ Detect clinical history form. This test is only for individuals who have been diagnosed with cancer.

Why are you ordering this test?

☐ New cancer diagnosis ☐ Past cancer diagnosis ☐ Cancer recurrence
☐ Current treatment monitoring ☐ Cancer metastasis

Type of Cancer	Age diagnosed	Tumor Status at Diagnosis		Current Tumor Status	
		Stage (TNM)	Grading (G)	Stage (TNM)	Grading (G)
Breast					
Ovarian					
Colorectal					
Melanoma					
Lung					
Other*: _____					

**Examples: endometrial, pancreatic, renal, gastric, sarcoma, aggressive prostate, etc.*

PATHOLOGY RESULTS: ☐ No pathology has been done at this time

HORMONAL/PROTEIN STATUS

☐ ER+ ☐ PR+ ☐ HER2+ ☐ KI67+ % POSITIVE_____
☐ ER- ☐ PR- ☐ HER2- ☐ KI67-

Previous tumor genotyping**:_____

Other immunohistochemical (IHC) staining **:_____

Other genetic testing results**:_____
Including cytogenetic and FISH analysis results.

Other histology results**: _____
** If testing has been performed previously, please attach a copy of the report

TNM Classifications
T - Primary Tumor (TX-T4)
N - Lymph Nodes (NX-N3)
M - Metastasis (M0 or M1)

Tumor Grading
GX - Grade cannot be assessed
G1 - Well differentiated
G2 - Moderately differentiated
G3 Poorly differentiated
G4 - Undifferentiated

HAS THE PATIENT PREVIOUSLY HAD HEREDITARY CANCER TESTING?: ☐ yes (attach results) ☐ no (skip this section)

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

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

☐ Other hereditary cancer testing: Type: _____ *Result:_____

*Please attach a copy of test results to this form. If results are from a family member, please indicate relationship to patient (i.e.: sister, maternal aunt, paternal grandfather).

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Clinical History Questionnaire

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EXPLAIN THE PATIENT'S EXPOSURE HISTORY BELOW: (MARK ALL THAT APPLY)

☐ None

Daily Exposures

☐ Alcohol
Drinks/day: _____

☐ Cigarette smoking (tobacco use)
Packs/day: _____

☐ Radiation (radon, x-rays, gamma rays)
Length of exposure: _____

☐ Ultraviolet exposure (tanning beds, sun exposure, sunburns)
Rate your exposure (high, medium, low):
_____

☐ Consume (eat) red meat
Meals per week: _____

☐ Diesel fuel

☐ Secondhand smoke
(i.e. living with a smoker)

☐ Genital use of talcum powder

Toxin and Work Exposures

☐ Arsenic # of years: _____

☐ Asbestos # of years: _____

☐ Chromium # of years: _____

☐ Nickel # of years: _____

☐ Silica dust # of years: _____

☐ Tar and soot # of years: _____

☐ Paint/solvent/chemicals # of years: _____

Other Exposure Information: _____

_____

_____

Occupation: _____

Examples: Coal miner, steel mill worker, flight attendant, pilot, doctor, accountant, researcher, etc.

PERSONAL MEDICAL INFORMATION: (MARK ALL THAT APPLY)

Date of last mammogram: _____ Result: _____ ☐ N/A

Date of last colonoscopy: _____ Result: _____ ☐ N/A

Total number of pregnancies: _____ Number of children (live births): _____

Age at time of first birth: _____ Age at menarche (first menstrual cycle) _____ Age at menopause: _____

Mark all conditions that apply to you:

☐ Acute and chronic pancreatitis

☐ Asthma

☐ Chronic hepatitis B

☐ Chronic hepatitis C

☐ Chronic obstructive pulmonary disease (COPD)

☐ Cirrhosis

☐ Colon/ rectal polyps

☐ Diabetes

☐ Endometriosis

☐ HIV

☐ Hormone use (i.e. fertility drugs, hormone replacement therapy)

☐ Idiopathic pulmonary fibrosis

☐ Infectious agents

☐ Inflammatory bowel disease (ulcerative colitis or Crohn's)

☐ Liver disease

☐ Obesity

☐ Pelvic inflammatory disease

Other conditions: _____

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CANCERINTERCEPT™ MONITOR

Clinical History Questionnaire

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TREATMENT INFORMATION: (MARK ALL THAT APPLY)

☐ This patient has not received any treatment thus far

☐ Hormone Therapy: _____

Date(s): _____ Cycle(s)/duration: _____ Last Treatment: _____

☐ Targeted Therapy: _____

Date(s): _____ Cycle(s)/duration: _____ Last Treatment: _____

☐ Chemotherapy: _____

Date(s): _____ Cycle(s)/duration: _____ Last Treatment: _____

☐ Radiation Therapy: _____

Date(s): _____ Cycle(s)/duration: _____ Last Treatment: _____

☐ Radiation Therapy: _____

Date(s): _____ Cycle(s)/duration: _____ Last Treatment: _____

☐ Other (type): _____

☐ Surgical resection (provide any relevant information): _____

☐ Date/ type of patient's last: Blood transfusion | stem cell transplant _____

Other medications/ supplements (type and dose): _____

Other relevant medical history: _____

_____

_____

FAMILY HISTORY:

☐ No Family History Available

Maternal	Paternal	Relationship	Cancer type or Condition	Age of Diagnosis
☐	☐			
☐	☐			
☐	☐			
☐	☐			
☐	☐			
☐	☐			

▶ Patient Signature: _____ ▶ Physician Signature: _____ Date: _____

Print: _____ Print: _____

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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.

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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.

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