GENESYS Diagnostics INC.

Hereditary Cancer Next Generation Sequencing Requisition Form

*Information required for testing

Patient Information

LAST NAME* | FIRST NAME* | MI | DOB* (MM/DD/YYYY) | SEX | GENDER

ADDRESS | CITY | STATE | ZIPCODE | PHONE NUMBER | EMAIL ADDRESS

Billing Information (Please include a copy of insurance card(s) for billing purposes.)

*☐ CLIENT BILL ☐ INSURANCE ☐ SELF PAY ☐ MEDICARE/MEDICAID (☐ PRIMARY ☐ SECONDARY) RELATIONSHIP: ☐ SELF ☐ SPOUSE ☐ DEPENDENT

INSURANCE NAME | MEMBER/POLICY ID | GROUP #

POLICY HOLDER NAME | POLICY HOLDER DOB (MM/DD/YYYY) | TEST INDICIATIONS/ICD-10 CODES*

Account Information

FACILITY/PRACTICE NAME* | PHONE NUMBER | FAX NUMBER | ORDERING PHYSICIAN NAME*

Specimen Information PREFERRED SPECIMEN IS BUCCAL SWAB

☐ BLOOD IN EDTA (5ml MIN) ☐ BUCCAL SWAB ☐ DNA (10 ug MIN) COLLECTION DATE:_____MM/DD/YYYY___ COLLECTION TIME:_____00:00 AM/PM_____

Background Information (Please check all that apply)

RACE AND ETHNICITY: ☐ WHITE ☐ ASIAN ☐ HISPANIC ☐ AFRICAN AMERICAN ☐ ASHKENAZI JEWISH ☐ OTHER (PLEASE SPECIFY):_____

GENE PANEL NAME* (Must choose one)	GENES**
☐ FULL HEREDITARY CANCER PANEL (99 GENES)	AIP, ALK, APC, ATM, BAP1, BARD1, BLM, BMPR1A, BRCA1, BRCA2, BRIP1, BUB1B, CDC73, CDH1, CDK4, CDKN1B, CDKN1C, CDKN2A, CEBPA, CEP57, CHEK2, CYLD, DDB2, DICER1, DIS3L2, EGFR, EPCAM, ERCC2, ERCC3, ERCC4, ERCC5, EXT1, EXT2, EZH2, FANCA, FANCB, FANCC, FANCD2, FANCE, FANCF, FANCG, FANCI, FANCL, FANCM, FH, FLCN, GATA2, GNAS, GPC3, HRAS, KIT, MAX, MEN1, MET, MLH1, MSH2, MSH6, MUTYH, NBN, NF1, NF2, NSD1, PALB2, PHOX2B, PMS2, POLD1, POLE, PRF1, PRKAR1A, PTCH1, PTEN, RAD50, RAD51C, RAD51D, RB1, RECQL4, RET, RHBDF2, RUNX1, SBDS, SDHA, SDHAF2, SDHB, SDHC, SDHD, SLX4, SMAD4, SMARCB1, STK11, SUFU, TMEM127, TP53, TSC1, TSC2, VHL, WRN, WT1, XPA, XPC
☐ BREAST AND GYNECOLOGICAL CANCER PANEL (33 GENES)	ATM, BARD1, BLM, BRCA1, BRCA2, BRIP1, CDC73, CDH1, CHEK2, DICER1, EPCAM, EZH2, FANCC, FANCM, FH, MLH1, MSH2, MSH6, MUTYH, NBN, NF1, PALB2, PMS2, POLD1, PRKAR1A, PTEN, RAD50, RAD51C, RAD51D, SDHB, SDHD, STK11, TP53
☐ BREAST CANCER PANEL (19 GENES)	ATM, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, FANCC, FANCM, MUTYH, NF1, PALB2, PTEN, RAD51C, RAD51D, SDHB, SDHD, STK11, TP53
☐ COLORECTAL AND GASTRICCANCER PANEL (43 GENES)	APC, ATM, BLM, BMPR1A, BRCA1, BRCA2, BUB1B,CDC73, CDH1, CDK4, CDKN1B, CDKN1C, CDKN2A, CEP57, CHEK2, EPCAM, FANCC, FLCN, GNAS, GPC3, KIT, MEN1, MLH1, MSH2, MSH6, MUTYH, NBN, NF1, NSD1, PALB2, PMS2, POLD1, POLE, PTEN, RHBDF2, SDHA, SDHB, SDHC, SDHD, SMAD4, STK11, TP53, VHL
☐ COMMON HEREDITARY CANCER PANEL (41 GENES)	APC, ATM, BAP1, BARD1, BMPR1A, BRCA1, BRCA2, BRIP1, CDH1, CDK4, CDKN2A, CHEK2, DICER1, EPCAM, KIT, MEN1, MLH1, MSH2, MSH6, MUTYH, NBN, NF1, PALB2, PMS2, POLD1, POLE, PTEN, RAD50, RAD51C, RAD51D, RET, SDHA, SDHB, SDHC, SDHD, SMAD4, STK11, TP53, TSC1, TSC2, VHL
☐ NERVOUS SYSTEM AND ENDOCRINE CANCER PANEL (44 GENES)	AIP, ALK, APC, BAP1, CDC73, CDKN1B, CDKN1C, CHEK2, DICER1, EPCAM, EZH2, FH, GNAS, GPC3, HRAS, MAX, MEN1, MLH1, MSH2, MSH6, NBN, NF1, NF2, NSD1, PHOX2B, PMS2, PRKAR1A, PTCH1, PTEN, RB1, RET, SDHA, SDHAF2, SDHB, SDHC, SDHD, SMARCB1, SUFU, TMEM127, TP53, TSC1, TSC2, VHL, WRN
☐ RENAL AND URINARY TRACT CANCER PANEL (39 GENES)	ATM, BAP1, BRCA1, BRCA2, BRIP1, BUB1B, CDC73, CDKN1C, CEP57, CHEK2, DICER1, DIS3L2, EPCAM, FANCA, FH, FLCN, GPC3, HRAS, MET, MLH1, MSH2, MSH6, NBN, NSD1, PALB2, PMS2, PTEN, RAD51D, SDHA, SDHB, SDHC, SDHD, SMARCB1, TMEM127, TP53, TSC1, TSC2, VHL, WT1
☐ INDIVIDUAL GENE TESTING	INDICATE BY CIRCLING GENES ABOVE OR LISTING_____

Patient Authorization and Consent

It has been explained to me and I understand that I am voluntarily providing a specimen for a genetic test. I will provide the specimen in a collection device provided by Genesys. My DNA will be extracted from my specimen at Genesys, and the test will evaluate how my genome variations may lead to a higher risk for cancer. The Genesys test will look for common genetic variations in genes that are prone to cancer risk. The test identifies the most common variants of these genes but is not designed to identify some rare mutations which may also affect cancer risk. The test is a clinical laboratory test and may aid in my treatment plan; therefore, I or my health insurer will be billed for this test. A written report of the test results will be provided to my health care provider who will inform me of the results. Genesys will keep all my medical information confidential and only disclose it to pursuant to applicable state and federal laws. I understand that I am responsible for providing accurate information about my insurance to Genesys Diagnostics Inc. I understand that Genesys Diagnostics Inc. will be providing testing service and billing my insurance. However, I understand that charges that are not covered by my insurance, including any applicable copayments and deductibles are my responsibility and I agree to pay such charges promptly.

Patient/Guardian Signature:* Date:*

☐ I do not consent to having my deidentified DNA sample used for internal research purposes.

Healthcare Provider Authorization

I certify that (i) this test is medically necessary, (ii) the patient (or authorized representative on the patient's behalf) has given informed consent (which includes written informed consent or written authorization when required by law) to have this testing performed, and (iii) the informed consent obtained from the patient meets the requirements of applicable law. I agree to provide Genesys, or its designee, any and all additional information reasonably required for this testing to be performed.

Healthcare Provider Signature:* Date:*

Medical Necessity Statement: Tests ordered on Medicare patients must follow CMS rules regarding medical necessity and FDA approval guidelines and must include diagnosis, symptoms and reason for testing as indicated in the medical record. If testing does not come under Medicare guidelines for payment a 'signed' Advanced Beneficiary Notice must be included.

**Certain regions in various genes have poor coverage and are not included in the panel (if you would like more coverage information regarding any specific genes of interest, please contact Genesys Diagnostics Inc.). All genes that have pseudogenes will have poorer performance on the MiSeq instrument. Variants in genes with pseudogenes may not be reliably detected. DNA alterations in regions not covered by this test such as deep intronic or regulatory regions, or in poorly covered regions will not be detected using Next Generation Sequencing analysis. There are technical limitations on the ability of Next Generation Sequencing to detect small insertions and deletions and these types of alterations are not detected as reliably as single nucleotide variants. This assay is not designed or validated for the detection of low-level mosaicism or somatic mutations.

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Hereditary Cancer Next Generation Sequencing Requisition Form

Patient Name_____ **Patient DOB**_____

Please read and answer the questions below carefully. While answering consider relatives who are living along with those who have passed away, those who are sick and those in remission, male and female relatives, and relatives on both your mother's and fathers' side of the family. Relatives refer to blood relatives and include mother, father, son, daughter, brother, sister, half-brother, half-sister, uncle, aunt, nephew, niece, grandparent, grandchild, and cousin.

Disease/Condition (ICD10 Code)	Self (Circle Response)	Relatives (Indicate Maternal or Paternal side)	Age at diagnosis
Breast Cancer	Yes / No		
Ovarian Cancer	Yes / No		
Colorectal Cancer	Yes / No		
Endometrial/ Uterine Cancer	Yes / No		
Pancreatic Cancer	Yes / No		
Prostate Cancer	Yes / No		
Colon Cancer	Yes / No		
Any other chronic or genetic diseases that run in your family:_____	Yes / No		
Any other cancer not mentioned above:_____	Yes / No		

PREVIOUS GENETIC TESTING

If genetic testing HAS been done please fill out table below ☐ Check here if NO genetic testing has been done

Gene:	RefSeq#:	Variant:	Genebank Reference #:
Gene:	RefSeq#:	Variant:	Genebank Reference #:
Gene:	RefSeq#:	Variant:	Genebank Reference #:
(Provide HGVS Nomenclature or indicate if other)			
Proband Name:	DOB (MM/DD/YYY):		Lab or clinic Family #:
Relationship to Patient:			

Answering these questions does not guarantee that your insurance will cover a cancer screening. The screening is a predictive test that can identify if you are at increased risk for certain types of cancer. It does not diagnose cancer or determine definitely if you will develop cancer in your lifetime.

ICD-10 CODES*			
☐C25.9	Malignant neoplasm of pancreas, unspecified	☐Z85.43	Personal history of malignant neoplasm of ovary
☐C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung	☐Z85.46	Personal history of malignant neoplasm of prostate
☐C50.919	Malignant neoplasm of unspecified site of unspecified female breast	☐Z85.89	Personal history of malignant neoplasm of organs and systems
☐C50.929	Malignant neoplasm of unspecified site of unspecified male breast	☐Z80.0	Family history of malignant neoplasm of digestive organs
☐C56.1	Malignant neoplasm of right ovary	☐Z80.1	Family history of malignant neoplasm of trachea, bronchus and lung
☐C56.2	Malignant neoplasm of left ovary	☐Z80.3	Family history of malignant neoplasm of breast
☐C56.9	Malignant neoplasm of unspecified ovary	☐Z80.41	Family history of malignant neoplasm of ovary
☐C61	Malignant neoplasm of prostate	☐Z80.42	Family history of malignant neoplasm of prostate
☐Z85.3	Personal history of malignant neoplasm of breast		