GenesisLabs
LABORATORY OF CHOICE

Genesis Labs
1912 Highway 35,
Oakhurst, NJ 07755
P 732 389 1530
F 732 389 0352

Accession Info (*For Genesis Lab Use*)

Primarius Pathology

Genesis Cancer Predisposition Panel

Date/Time Received _____

Specimen Information (For office use only)

Collection Date: _____

Collection Time: _____ ☐ AM ☐ PM

Specimen ID # (on tube) _____

Med. Record Number/ID # _____

Patient Information

Last Name _____ First Name _____ MI _____ DOB _____ Gender _____

Address _____

City/State/Postal Code _____

Ethnicity (Optional)
☐ African American/Black ☐ East Asian ☐ South Asian
☐ Ashkenazi Jewish ☐ Hispanic ☐ Native American
☐ Caucasian/White ☐ Middle Eastern ☐ Other _____

Phone _____

Email _____

Ordering Provider Information

Facility Name _____

Facility Address _____

City/State/Postal Code _____

NPI# _____

Ordering Physician (full name) _____

Telephone _____ Fax _____

Email _____

Referring Physician _____

Telephone _____ Fax _____

Email _____

Billing Information

Required: Include copy of both sides of patient's Insurance card(s)

☐ **Insurance Billing**

Policy Holder Name _____

Primary Insurance Company Name _____

Primary Member ID# _____

Primary Group# _____

Insurance Phone# _____

Patient Relation to Policy Holder

☐ Self ☐ Spouse ☐ Child ☐ Other _____

Secondary Insurance Company Name _____

Secondary Member ID# _____

Secondary Group# _____

Insurance Phone# _____

☐ **Institutional Billing**

Facility Name _____

Contact Name _____

Facility Address _____

Telephone/Fax/Email _____

☐ **Patient Payment**

Contact Name _____

Telephone _____

Email _____

☐ Check ☐ Credit Card ☐ Invoice

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Patient Clinical Information & Cancer History

ICD-10 code (required): _____

Interprofessional Consultation (CPT: 99451/99452). I would like to have an independent medical geneticist review and provide advice on my patients' genetic test results. *To opt-out, check here:* ☐ *(opt-out)*

If there's no personal history of cancer, check here: ☐ None Is patient affected and/or showing symptoms? ☐ Yes (Fill out below) ☐ No

Patient Dianosis	Is currently being treated?	Age of Diagnosis	Pathology/Clinical Information (Select all that apply)
☐ Colon/Rectal Cancer	☐ Yes ☐ No	_____	Type: ☐ Mucinous ☐ Signet Ring ☐ Medullary Growth Pattern ☐ Tumor Infiltrating Lymphocytes ☐ Crohn's-like Lymphocytic Reaction ☐ Tumor MSI-High or Abnormal IHC Results _____ ☐ Tumor not available for MSI or IHC testing _____
☐ Colon/Rectal Adenomas	☐ Yes ☐ No	_____	Cumulative Adenomatous Polyp # ☐ 1 ☐ 2-5 ☐ 6-9 ☐ 10-19 ☐ 20-99 ☐ 100+
☐ Prostate Cancer	☐ Yes ☐ No	_____	Gleason Score: _____ ☐ Metastatic
☐ Breast Cancer ☐ Left ☐ Right	☐ Yes ☐ No	_____	☐ Ductal Invasive ☐ Bilateral ☐ Triple-Negative (ER-,PR-,HER2-) ☐ DCIS ☐ Lobular Invasive ☐ Metastatic: HER2 Status: ☐ + ☐ - Previous Chemotherapy: ☐ Yes ☐ No Previous Endocrine Therapy if ER/PR+: ☐ Yes ☐ No ☐ N/A
☐ Ovarian Cancer	☐ Yes ☐ No	_____	☐ Non-epithelial
☐ Uterine/Endometrial Cancer	☐ Yes ☐ No	_____	☐ Tumor MSI-High or Abnormal IHC Results _____ ☐ Tumor not available for MSI or IHC testing _____
☐ Other Cancer Type(s)	☐ Yes ☐ No	_____	List Type: _____
☐ Cancer Syndrome(s)	☐ Yes ☐ No	_____	List Type: _____

Additional summarization/comments regarding symptoms, medical history, and/or previous testing below:

_____

_____

_____

Family History

Is there a family history of current disease in which the patient is being tested for? ☐ NO ☐ YES (fill below)

Relation to Patient	Maternal	Paternal	Diagnosed Condition	Diagnosed Age
	☐	☐		
	☐	☐		
	☐	☐		
	☐	☐		
	☐	☐		
	☐	☐		

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Test Selection

Please select ONE of the tests from the menu below

Test Selection	# of Genes	Gene List
☐ Comprehensive Hereditary Cancer (*Full Panel*) Includes all cancer subtypes listed below	53	AIP, APC, ATM, BAP1, BARD1, BLM, BMPR1A, BRCA1, BRCA2, BRIP1, CDH1, CDKN2A, CHEK2, DICER1, FANCC, FH, FLCN, KIT, MAX, MEN1, MLH1, MRE11, MSH2, MSH6, MUTYH, NBN, NF1, NF2, PALB2, PMS2, POLE, POT1, PRKAR1A, PTCH1, PTEN, RAD50, RAD51C, RAD51D, RB1, RET, SDHA, SDHB, SDHC, SDHD, SMAD4, STK11, TMEM127, TP53, TSC1, TSC2, VHL, WT1, XRCC2
If full panel NOT selected please select ONE panel below (If more than one is selected it will be treated as the full comprehensive panel)		
☐ Colorectal/Gastric	24	ATM, APC, BLM, BMPR1A, CDH1, CHEK2, FANCC, KIT, MLH1, MSH2, MSH6, MUTYH, NF1, PALB2, PMS2, PTEN, POLE, SDHA, SDHB, SDHC, SDHD, SMAD4, STK11, TP53
☐ Pancreatic	20	APC, ATM, BRCA1, BRCA2, BMPR1A, CDKN2A, FANCC, MEN1, MLH1, MSH2, MSH6, NF1, PALB2, PMS2, SMAD4, STK11, TP53, TSC1, TSC2, VHL
☐ Prostate	14	ATM, BRCA1, BRCA2, BRIP1, CHEK2, MLH1, MSH2, MSH6, NBN, PALB2, PMS2 RAD51C, RAD51D, TP53
☐ Breast/Gynecological	29	ATM, BARD1, BLM, BRCA1, BRCA2, BRIP1, CDH1, CDKN2A, CHEK2, DICER1, FANCC, FH, MLH1, MRE11, MSH2, MSH6, MUTYH, NBN, NF1, PALB2, PMS2, POLE, PTEN RAD50, RAD51C, RAD51D, STK11, TP53, XRCC2
☐ Renal	20	BAP1, CDKN2A, DICER1, FH, FLCN, MLH1, MSH2, MSH6, PMS2, PTEN, SDHA, SDHB, SDHC, SDHD, TMEM127, TP53, TSC1, TSC2, VHL, WT1
☐ Brain	21	AIP, APC, BAP1, BRCA2, DICER1, MEN1, MLH1, MSH2 ,MSH6, NBN, NF1, NF2, PMS2, POT1, PTCH1, PTEN, RB1, TP53, TSC1, TSC2, VHL
☐ Melanoma	9	BAP1, BRCA1, BRCA2, CDKN2A, POLE, POT1, PTEN, RB1, TP53
☐ Endocrine	18	AIP, APC, CHEK2, DICER1, FH, MEN1, NF1, RET, SDHA, SDHB, SDHC, SDHD, PRKAR1A, PTEN, TP53, VHL, MAX, TMEM127

Panel/Test Limitations:

This test is designed to sequence 99.878% of bases in the coding regions (exons) of the 53 genes listed and their corresponding +/-3 base pairs (bp) of intronic regions surrounding each exon. The test identifies single nucleotide variants (SNVs) and small insertion/deletions (delins) in the coding regions (exons). A list of genes with regions not sequenced, including the specific genomic coordinates, are available upon request. This test has a sensitivity of greater than 99.999% and specificity of greater than 99.999% for SNVs in the sequenced regions of this test. Sensitivity for detecting delins up to 15 bp is greater than 0.99. Due to limitations in technology, certain types of genomic variants are not identified such as, large delins, rearrangements (for example the test does not detect the Boland inversion in the MSH2 gene), copy number variants, such as deletions and duplications, non-coding sequence such as intronic or intergenic regions, structural variation, somatic mosaicism, or epigenetic events such as methylation. Due to the limitations of identifying the exact length of homopolymers (e.g. (A)n or (T)n) with this sequencing methodology, deletions or insertions of one base pair in these regions may be false positive errors. Such deletions and insertions are thus reported with lower confidence for homopolymers of four to six base pairs and are not reported for homopolymers of seven and more base pairs. False negative results may occur if known pathogenic variants are in regions not sequenced, if they are present in non-uniquely mappable regions, such as exons 12-15 in the PMS2 gene, are of low coverage or are otherwise determined to be of low quality. Variants with a high likelihood of arising from a pseudogene in the PMS2 gene are not reported. Exon 28 and 53 of ATM, exon 13 of BRIP1, exon 1 of KIT, exon 12 of MLH1, exon 15 of MRE11, exon 1 of NF1, exon 1 of NF2, exon 1 of PTCH1, exon 1 of PTEN, exon 13 of RET, exon 1 of SDHA, exon 2 of TMEM127, and exon 1 of WT1 are not fully covered by this test, therefore pathogenic variants may not be detected in these genes. Variants are not orthogonally confirmed. Indeterminate results may be reported if a variant cannot be confidently identified. There is a small chance that a false positive may result from clonal hematopoiesis of indeterminate potential (CHIP), especially in older individuals. Results represent the tissue type used for this analysis and may not reflect variation in other tissue types. Sequence variation is compared to reference data using genome build GRCh38. This analysis is based on the coding regions (exons) and canonical splice regions of the 53 genes included in the test and does not predict risks associated with other genes not included in the test or in regions not sequenced.

MEDICAL PROVIDER SIGNATURE OF MEDICAL NECESSITY:

My signature below certifies that I am a licensed physician or authorized healthcare provider. I determined that the test listed above is medically necessary for the care and treatment of my patient. I explained to the patient the benefits, limitations, and risks of the test and have answered any questions before obtaining the patients informed consent.

Signature **Date (MM/DD/YY)**

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Introduction:

Testing for hereditary genetic conditions can be a complex process. This form describes the benefits, risks, and limitations of testing for susceptibility to hereditary genetic conditions. This test is voluntary, and it is recommended that you receive genetic counseling from a licensed healthcare provider who can answer your questions about genetic testing and provide information about alternatives. Information about genetic counselors in your area is available at https://www.nsgc.org/.

Purpose:

Genetic testing is performed to identify changes in the DNA sequence in genes that are associated with the risk for developing hereditary cancer. This test will help determine if a person has a significantly increased risk of developing certain tumors due to a mutation or mutations in cancer-predisposed genes. Cancer risk is not always definitive and not everyone who has a gene mutation will develop cancer, nor are individuals without a gene mutation immune from one day developing cancer. Genetic testing allows a more accurate estimate of an individual's risk for hereditary cancer than family history alone. Genetic counseling is always recommended prior to participating in genetic testing, as well as after test results are received.

Test Procedure:

A saliva sample will be obtained and sent to Genesis Labs for genetic testing. Specific genes will be analyzed to look for genetic variations (mutations) based off the test selected. This form is for you to consent to the specific tests that in which your physician ordered based on the requisition. Testing is only performed to cover reported relevant genomic areas, and the presence of abnormalities outside these tested areas cannot be ruled out. I further understand that the sample provided will be destroyed at the end of the testing process or not more than sixty (60) days after analysis, or permanently stripped of identifying information and used for research purpose or test validation studies. I understand that because of the de-identification, such research sample cannot be linked to me or information that I have provided. If you are a patient in the State of New York, your sample will be destroyed at the end of the testing process or not more than 60 days after the sample was taken.

Benefits:

Genetic testing for hereditary cancer is one way you may be able to learn more about your risk for developing certain hereditary cancers. Your test results may help you and your doctor make more informed choices about your health care, which may help in treatment approaches or in devising prevention strategies. In addition, the identification of gene mutation(s) in a family enables other blood relatives to determine whether they share the same hereditary cancer risks.

Risks:

The test is a genetic screening test that may cause you to discover sensitive information about your health or disease risks, including risk for diseases that currently have no treatment. Learning that you have a genetic mutation may be upsetting and may increase feelings of anxiety, depression, and vulnerability that may lead to difficult decisions regarding your medical care. Additional risks associated with test results include the possibility that an error in testing may occur that may affect your results. While the tests are highly sensitive and specific, there is always a small chance that an error may occur.

Limitations:

This test analyzes only the specific genes that are known to be associated with the risk of developing hereditary cancer as stated on the requisition. You may have mutations in genes that are not included in this test. If no mutation is found, you may still be at risk for hereditary cancer due to a genetic predisposition that cannot be detected by this test, either in the gene you were tested for or in another gene linked to hereditary cancer. Certain regions of DNA may not be well covered and may not be able to detect all DNA changes due to limitations in current technology. It is also possible that you may have mutations in genes whose impact on the risk for developing hereditary cancer is currently unknown, referred to as variants of unknown significance (VUS). If your test results are positive, or inconclusive, there may be differing opinions among physicians about the best steps to take. Your medical care is best determined by you in consultation with your healthcare provider.

Test Results:

Test results will be issued as a single clinical report for the patient. Based on your results, you and your physician can make more informed choices about your health care. Possible results of this test include:

Positive/Likely Positive result – Result indicates that one or more genetic variants were identified in association to an increased risk of developing hereditary cancer in the future.

Negative/Likely Negative result – Result indicates that no genetic variant was identified by this test. This reduces the likelihood of, but does not exclude the possibility of, the disease being genetic in nature. You 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) for which you were tested or in another gene linked to hereditary cancer.

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Uncertain result / Variant of uncertain significance (VUS) - A variant of uncertain significance was identified by this test, but it is not known if this change is linked to an increased risk to cancer. This means that a genetic variant was identified but based on available information in the medical literature and research and scientific databases, it is not certain whether the variant may have an association to cancer. Without further information, the effects of the variant cannot be known. The uncertainty may be resolved over time if additional information becomes available. Periodic reanalysis of the sequence data or further analysis, including testing of additional family members, may be recommended.

Indeterminate result - An indeterminate result indicates that there were relevant genetic variant(s) identified in the analysis, but that there is uncertainty as to whether they are true variants or artifacts. Furthermore, it is considered that a repeat test will not resolve the technical uncertainty and orthogonal confirmation is necessary to resolve the result.

Inadequate result - Result indicates that there was an issue with the patient sample that resulted in data that the lab cannot interpret. It is considered that a repeat test will likely resolve the technical uncertainty and therefore a repeat sample is recommended to complete the analysis.

All reportable variants in the clinical report will be categorized as pathogenic, likely pathogenic or a variant of uncertain significance (VUS) utilizing the American College of Medical Genetics and Genomics (ACMG)/Association for Molecular Pathology (AMP) guidelines as published by Richards et al 2015 (for more information see: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4544753/). If and when gene symbols are updated, Variantyx, Inc., will report on the most updated HGNC official gene symbols. Variants may have a strong phenotypic correlation with the reported patient phenotype(s) and be considered a strong causal candidate for the disorder or may have some phenotypic overlap with the reason for testing but not be considered the sole genetic cause for the phenotype(s) in the patient. Both types of variants may be reported. Even if this test finds DNA changes that are responsible for the reported symptoms, the testing may not completely predict the severity of the disorder, possible future problems, or response to treatment.

Test Payment:

Health insurance providers often reimburse genetic testing of appropriate individuals who are deemed necessary by their physician. You are responsible for any cost of the genetic test not reimbursed by insurance, and it is recommended that you contact your insurance company to determine coverage prior to consenting to genetic testing.

Patient (or Guardian if applicable) Consent

By signing this consent form, I agree to the following:

- I have read this document in its entirety and understand I may request a copy for my records.
- I have had the opportunity to ask questions and discussed with my healthcare provider the benefits, risks, and limitations of the genetic test to be performed as indicated on the associated test requisition form ordered by my healthcare provider.
- I have been informed about the availability and importance of genetic counseling.
- I acknowledge that the test results will be communicated to me and my physician and/or genetic counselor privately and will not be released to another party without my consent or authorization.
- I affirm that I have given consent to my treating physician, to communicate with a specialist about the results of my genetic test, and I am aware of the applicable cost-sharing.

My signature below acknowledges my voluntary participation for genetic testing for predisposition to hereditary cancer. I understand that the genetic analysis performed is specific only for this disease and in no way guarantees my health, or the health of other family members.

Patient Name (printed) | **Date of Birth**

Signature of Patient (or Legal Guardian) | **Date and Time of Signature**