BAYLOR GENETICS

**BAYLOR GENETICS**
2450 HOLCOMBE BLVD.
GRAND BLVD. RECEIVING DOCK
HOUSTON, TX 77021-2024

**PHONE**
1.800.411.4363
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1.800.434.9850

**CONNECT**

# HEREDITARY CANCER REQUISITION

## PATIENT INFORMATION (COMPLETE ONE FORM FOR EACH PERSON TESTED)

Patient Last Name | Patient First Name | MI | Date of Birth (MM / DD / YYYY)

Address | City | State | Zip | Phone

Accession # | Hospital / Medical Record #

Patient discharged from the hospital/facility: ◯ Yes ◯ No

Biological Sex: ◯ Female ◯ Male ◯ Unknown

Gender identity (if different from above):

## REPORTING RECIPIENTS

Ordering Physician | Institution Name

Email (Required for International Clients) | Phone | Fax

### ADDITIONAL RECIPIENTS

Name | Email | Fax

Name | Email | Fax

## PAYMENT (FILL OUT ONE OF THE OPTIONS BELOW)

◯ **SELF PAYMENT**

☐ Pay With Sample ☐ Bill To Patient

◯ **INSTITUTIONAL BILLING**

Institution Name | Institution Code | Institution Contact Name | Institution Phone | Institution Contact Email

◯ **INSURANCE**

☐ Do Not Perform Test Until Patient is Aware of Out-Of-Pocket Costs (excludes prenatal testing)*

*If patient does not agree to out-of-pocket costs, the Baylor Genetics Billing Team will contact the clinician and/or patient for additional billing options prior to cancelling the test.

**REQUIRED ITEMS** 1. Copy of the Front/Back of Insurance Card(s) 2. ICD10 Diagnosis Code(s) 3. Name of Ordering Physician 4. Insured Signature of Authorization

Name of Insured | Insured Date of Birth (MM / DD / YYYY)

Patient's Relationship to Insured | Phone of Insured

Address of Insured

City | State | Zip

Primary Insurance Co. Name | Primary Insurance Co. Phone

Primary Member Policy # | Primary Member Group #

Name of Insured | Insured Date of Birth (MM / DD / YYYY)

Patient's Relationship to Insured | Phone of Insured

Address of Insured

City | State | Zip

Secondary Insurance Co. Name | Secondary Insurance Co. Phone

Secondary Member Policy # | Secondary Member Group #

By signing below, I hereby authorize Baylor Genetics to provide my insurance carrier any information necessary, including test results, for processing my insurance claim. I understand that I am responsible for any co-pay, co-insurance, and unmet deductible that the insurance policy dictates, as well as any amounts not paid by my insurance carrier for reasons including, but not limited to, non-covered and non-authorized services. I understand that I am responsible for sending Baylor Genetics any and all payments that I receive directly from my insurance company in payment for this test. Please note that Medicare does not cover routine screening tests.

Patient's Printed Name | Patient's Signature | Date (MM / DD / YYYY)

## STATEMENT OF MEDICAL NECESSITY (REQUIRED)

This test is medically necessary for the risk assessment, diagnosis, or detection of a disease, illness, impairment, symptom, syndrome, or disorder. The results will determine my patient's medical management and treatment decisions. The person listed as the Ordering Physician is authorized by law to order the test(s) requested herein. I confirm that I have provided genetic testing information to the patient and they have consented to genetic testing.

Physician's Printed Name | Physician's Signature | Date (MM / DD / YYYY)

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# HEREDITARY CANCER REQUISITION

Patient Last Name | Patient First Name | MI | Date of Birth (MM / DD / YYYY) | Biological Sex

## ETHNICITY

- ◯ African American
- ◯ Ashkenazi Jewish
- ◯ East Asian (China, Japan, Korea)
- ◯ Finnish
- ◯ French Canadian
- ◯ Hispanic American
- ◯ Mennonite
- ◯ Middle Eastern (Saudi Arabia, Qatar, Iraq, Turkey)
- ◯ Native American
- ◯ Northern European Caucasian (Scandinavian, UK, Germany)
- ◯ Pacific Islander (Philippines, Micronesia, Malaysia, Indonesia)
- ◯ South Asian (India, Pakistan)
- ◯ Southeast Asian (Vietnam, Cambodia, Thailand)
- ◯ Southern European Caucasian (Spain, Italy, Greece)
- ◯ Other (Specify): _____

## SAMPLE

### SAMPLE TYPE

- ◯ Blood in EDTA (Purple-top)
- ◯ DNA (Specify): _____
- ◯ Buccal Swab
- ◯ Saliva

Date of Collection: ____ / ____ / ____
MM DD YYYY

**NOTE:** Extracted DNA/RNA will only be accepted if the isolation of nucleic acids for clinical testing occurs in a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by the CAP and/or the CMS.

Blood should not be sent from patients who have had a bone marrow transplant or recent blood transfusion

## TESTING OPTIONS

☐ Targeted Sequencing for Known Familial Mutation (If selected, complete section below)

Proband Last Name | Proband First Name

Relationship to Proband | Date of Birth (MM/DD/YYYY)

Proband testing location (Select one)

- ◯ Baylor Genetics

Lab # | Family #

- ◯ Another Laboratory

1. Attach a copy of the Proband test results.
2. A positive control sample of the Proband is requested. Please provide, if available.

☐ Full Gene Sequencing

☐ Deletion/ Duplication Analysis

## INDICATION FOR TESTING (REQUIRED)

ICD10 Diagnosis Code(s) _____

☐ Personal History

Type of Cancer _____

Cancer Location _____

Age at Diagnosis _____

☐ Family History (include relationship to family member, cancer type, age at diagnosis)

## HEREDITARY CANCER TESTS

### HEREDITARY CANCER PANELS | 24001

| | TEST NAME | SAMPLE * |
|---|---|---|
| ☐ | Comprehensive Hereditary Cancer (94 genes) | BE, BUC, DNA, SA |
| ☐ | Common Hereditary Cancer (43 genes) | BE, BUC, DNA, SA |
| ☐ | BRCA1 & BRCA2 Panel (2 genes) | BE, BUC, DNA, SA |
| ☐ | High-Risk Hereditary Breast Cancer (9 genes) | BE, BUC, DNA, SA |
| ☐ | Hereditary Breast/Ovarian/Endometrial Cancer (27 genes) | BE, BUC, DNA, SA |
| ☐ | High-Risk Hereditary Colorectal Cancer (22 genes) | BE, BUC, DNA, SA |
| ☐ | Hereditary Colorectal/Gastrointestinal Cancer (37 genes) | BE, BUC, DNA, SA |
| ☐ | Hereditary Melanoma (10 genes) | BE, BUC, DNA, SA |
| ☐ | Hereditary Prostate Cancer (12 genes) | BE, BUC, DNA, SA |
| ☐ | Hereditary Paraganglioma/Pheochromocytoma (12 genes) | BE, BUC, DNA, SA |
| ☐ | Hereditary Renal Cancer (19 genes) | BE, BUC, DNA, SA |
| ☐ | Hereditary Endocrine Cancer (22 genes) | BE, BUC, DNA, SA |
| ☐ | Hereditary Pancreatic Cancer (21 genes) | BE, BUC, DNA, SA |
| ☐ | Hereditary Brain/Central Nervous System/Peripheral Nervous System Cancer (25 genes) | BE, BUC, DNA, SA |
| ☐ | Hereditary Leukemia/Lymphoma (18 genes) | BE, BUC, DNA, SA |

* Refer to Sample Specifications Table (Page 8)

Test list continued on next page

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# HEREDITARY CANCER REQUISITION

Patient Last Name | Patient First Name | MI | Date of Birth (MM / DD / YYYY) | Biological Sex

## HEREDITARY CANCER TESTS | 24001

### SINGLE GENE ANALYSIS

Most individual gene tests have sequencing and deletion/duplication studies along with the comprehensive analysis, which includes both sequencing and deletion/duplication. Only the comprehensive test codes are listed below. If requesting individual sequencing and/or deletion/duplications codes, please obtain the test code from our website and write in the below space(s).

Test Code | Gene | Test Code | Gene | Test Code | Gene

Test Name | Test Name | Test Name

| TEST CODE | TEST NAME | DISORDER | SAMPLE TYPE * |
|---|---|---|---|
| ☐ 6720 | *APC* Comprehensive (Sequence & Deletion/Duplication Analysis) | APC-Associated Polyposis Conditions | BE |
| ☐ 6520 | *RUNX1* Sequence Analysis | Familial Thrombocytopenia with Propensity to AML | BE |
| ☐ 3740 | *FH* Sequence Analysis | Hereditary Leiomyomatosis and Renal Cell Cancer (FH-Related Disorders) | BE, SA |
| ☐ 6705 | *MLH1* Comprehensive (Sequence & Deletion/Duplication Analysis) | Hereditary Non-Polyposis Colon Cancer (HNPCC) - Blood Analysis | BE |
| ☐ 6710 & 6888 | *MSH2* Comprehensive (Sequence & Deletion/Duplication Analysis) AND *EPCAM* Deletion/Duplication Analysis (by MLPA) | Hereditary Non-Polyposis Colon Cancer (HNPCC) - Blood Analysis | BE |
| ☐ 6715 | *MSH6* Comprehensive (Sequence & Deletion/Duplication Analysis) | Hereditary Non-Polyposis Colon Cancer (HNPCC) - Blood Analysis | BE |
| ☐ 6795 | PMS2 Deletion/Duplication Analysis | Hereditary Non-Polyposis Colon Cancer (HNPCC) | BE |
| ☐ 6890 | *PMS2* Comprehensive (Sequence & Deletion/Duplication Analysis) | Hereditary Non-Polyposis Colon Cancer (HNPCC) - Blood Analysis | BE |
| ☐ 6888 | *EPCAM* Deletion/Duplication Analysis (by MLPA) | Hereditary Non-Polyposis Colon Cancer (HNPCC) - Blood Analysis | BE |
| ☐ 6821 | *TP53* Comprehensive (Sequence & Deletion/Duplication Analysis) | Li-Fraumeni Syndrome (LFS) | BE |
| ☐ 3665 | *MEN1* Sequence Analysis | Multiple Endocrine Neoplasia, Type 1 | BE, SA |
| ☐ 3660 | *RET* Sequence Analysis | Multiple Endocrine Neoplasia, Type 2 (RET-Related Disorders) | BE, SA |
| ☐ 6120 | *MUTYH (MYH)* Sequence Analysis | MUTYH (MYH) - Associated Polyposis | BE |
| ☐ 6104 | *MUTYH (MYH)* Mutation Panel (2 Mutations) | MUTYH (MYH) - Associated Polyposis | BE |
| ☐ 3600 | *SDHB, SDHC, & SDHD* Sequence Panel | PHEO and PGL Syndromes | BE, SA |
| ☐ 6790 | *PTEN* Comprehensive (Sequence & Deletion/Duplication Analysis) | PTEN-Related Disorders | BE |
| ☐ 6121 | *RECQL4* Sequence Analysis | Rothmund-Thomson Syndrome (RECQL4 -Related Disorders) | BE |
| ☐ 6770 | *VHL* Comprehensive (Sequence & Deletion/Duplication Analysis) | Von Hippel-Lindau Syndrome | BE |

## SAMPLE SPECIFICATIONS TABLE

| ABBREVIATION | SAMPLE NAME | RECOMMENDED AMOUNT (2 YRS - ADULT) | RECOMMENDED AMOUNT (NEWBORN - 2YRS) | SHIPPING INSTRUCTIONS | SPECIAL NOTES |
|---|---|---|---|---|---|
| BE | Blood in EDTA tube (purple-top) | 3-5 cc | 2 -3 cc | Ship at room temperature in an insulated container by overnight courier. Do not heat or freeze. | |
| BUC | Buccal Swab | See Special Notes | See Special Notes | Ship at room temperature in an insulated container by overnight courier. Do not heat or freeze. Sample must arrive within 72 hours. | Collect with ORAcollect•Dx (OCD-100) self-collection kit (provided by Baylor Genetics with instructions). It is highly recommend that the sample be collected by a healthcare professional. |
| DNA | DNA, Extracted | 10 ug | 10 ug | Ship at room temperature in an insulated container by overnight courier. Do not heat or freeze. | |
| SA | Saliva | See Special Notes | See Special Notes | Ship at room temperature in an insulated container by overnight courier. Do not heat or freeze. | Collect with Oragene DNA Self-Collection Kit. |

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## INFORMED CONSENT FOR HEREDITARY CANCER TESTING

| Patient Last Name | Patient First Name | MI | Date of Birth (MM / DD / YYYY) | Biological Sex |
|---|---|---|---|---|
| | | | / / | |

Your physician has advised you to undergo genetic testing for hereditary cancer and is requesting testing for:

Name of Test

### HEREDITARY CANCER GENE TESTING CONSENT FORM

The purpose of this document is to provide information about the test. This information is meant to be used as a supplement to your discussion with a health care professional. If you agree to have genetic testing for hereditary cancer, you will be asked to sign the last page of this document, indicating that you understand the information provided and wish to have testing. You will be given a copy of this document for your records.

### DESCRIPTION OF GENETIC TESTING FOR HEREDITARY CANCER

Hereditary cancer is due to mutations (changes) in the DNA sequence of genes responsible for cell development. Mutations can be the result of a sequence change, missing/deleted segment, or extra/duplicated region of a gene. Multiple genes have been discovered and linked to an increased risk for developing various cancers. The purpose of genetic testing for hereditary cancer is to determine if you carry a mutation in a cancer susceptibility gene. Mutations in specific genes can be responsible for different hereditary cancer syndromes. Genetic testing is available to test for individual genes or multiple genes simultaneously as part of panel tests. The type of cancer and lifetime risk of developing cancer varies for each gene.

### INDICATIONS FOR TESTING

The decision to undergo genetic testing for hereditary cancer (single gene or gene panel analysis) is made by you and your physician. In general, single gene/panel analysis is first performed for an individual with cancer history suggestive of hereditary predisposition. You will be required to submit a sample (most likely blood) and DNA will be isolated and purified from this sample for genetic analysis. This testing is complex and utilizes specialized materials so that there is always a very small possibility that the test will not work properly or an error will occur requiring additional sample to be collected from you. If you are found to carry a mutation in a hereditary cancer gene, this may have implications for your family members and analysis of the specific gene in the family members may be recommended. This will require accurate information regarding biological relationship with your family members.

Pre-and post-test genetic counseling by a genetic specialist, such as a certified genetic counselor or medical geneticist, is highly recommended for all individuals undergoing genetic testing.

### TEST REPORTING

Results are confidential and will only be released to your designated physician or genetic counselor. Your results will not be released to other parties without your written consent. Testing cannot detect all types of mutations causing hereditary cancers or other genetic disorders, and results will only include the gene(s), and specific regions of the genes, ordered by your physician. Cancer screening and medical management options are available if a mutation is detected in a well-described hereditary cancer gene. Additional recommendations may become available as new therapies and discoveries emerge over time for hereditary cancers.

### TYPE OF RESULTS

There are various types of results that can be reported from genetic testing, including:

**Positive result** - A mutation was identified in a gene(s) that explains either the cause of your cancer history or the risk to develop cancer in the future. The specific type(s) of cancer will depend on the gene(s) involved. Your physician or genetic counselor will review cancer screening and medical management options based on current understanding of the gene(s) in which the mutation was found.

**Negative result** - No mutations were identified in the genes tested. Decisions for future cancer screening and medical management will be based on your personal and/or family history.

**Variant result** - A change was detected in one or more genes; however, there is limited information to determine if the change is associated with increased cancer risk, therefore, it is referred to as a variant. The laboratory will review the medical literature and provide information about any known clinical significance of the variant. Testing other close family members for the variant may be offered to determine significance. However, in some cases, significance remains unclear until more data is available.

In addition to hereditary cancer risk, some of the genes tested may be known to also cause other genetic conditions inherited in a recessive manner. This means that if you carry a mutation in one of these genes and your child's other biological parent carries a mutation in the same gene there is a 25% chance of having a child affected with one of these recessive conditions. Further testing may be recommended for you and your reproductive partner based on the results from a hereditary cancer test.

INITIAL _____

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## INFORMED CONSENT FOR HEREDITARY CANCER TESTING

Patient Last Name | Patient First Name | MI | Date of Birth (MM / DD / YYYY) | Biological Sex

### HEREDITARY CANCER GENE TESTING CONSENT FORM

#### PATIENT CONFIDENTIALITY AND SPECIMEN RETENTION

- Results will only be released to a licensed healthcare provider, to those allowed access to test results by law, and to those authorized in writing.
- In rare cases, persons with genetic diagnoses have experienced problems with insurance coverage and employment. The U.S. Federal Government has enacted several laws that prohibit discrimination based on genetic test results by health insurance companies and employers. In addition, these laws prohibit unauthorized disclosure of this information. For more information, you can visit www.genome.gov/10002077.
- Samples will be retained in the laboratory in accordance with the laboratory retention policy.
- After testing is complete, the de-identified submitted specimen may be used for test development and improvement, internal validation, quality assurance, and training purposes. DNA specimens are not returned to individuals or to referring heath care providers unless specific prior arrangements have been made.
- Samples from residents of New York State will not be included in the de-identified research studies described in this authorization and will not be retained for more than 60 days after test completion, unless specifically authorized by your selection. No tests other than those authorized shall be performed on the biological sample.
- Information including results, indications for testing and clinical status obtained from the Hereditary Cancer gene testing may be shared with health care providers, scientists and health care databases or used in scientific publications or presentations, but the personal identifying information of all persons studied will not be revealed in such data sharing or publications/presentations.

### RESEARCH & RECONTACT CONSENT

For more information on research at Baylor Genetics, please visit baylorgenetics.com. Please read the below statements carefully and check the appropriate box. Note: If left blank, consent is interpreted as "NO."

☐ I agree to use of my de-identified specimen for research to improve genetic testing for all patients and contribute to scientific research.

☐ I am a New York State Resident, and I give Baylor Genetics permission to store my specimen in accordance to the laboratory retention policy for internal quality assurance and possible research studies.

☐ In addition to agreeing above, I agree to be contacted by Baylor Genetics regarding research opportunities.

### PATIENT AUTHORIZATION

I have read the attached informed consent and I give permission to Baylor Genetics to perform genetic testing as described.

Patient Signature | Date (DD/MM/YYYY)

Patient's Legal Guardian Signature | Date (DD/MM/YYYY)

Relationship to Patient

Physician's Statement: I have explained the genetic testing specified to this individual. I have addressed the limitations outlined above, and I have answered this person's questions. I have obtained consent from the patient or the legal guardian for this testing.

Physician Signature | Physician Name | Date (DD/MM/YYYY)

Phone