

HEREDITARY CANCER GENETIC TEST REQUISITION FORM

PATIENT INFORMATION	
Patient Last Name: _____ Patient First Name: _____ MI _____	
Date of Birth (MM/DD/YY): _____ Sex <input type="checkbox"/> Male <input type="checkbox"/> Female	Ethnic Background (check all that apply)
Address: _____	<input type="checkbox"/> African American <input type="checkbox"/> Asian/Pacific Islander
City: _____ State: _____ Zip: _____	<input type="checkbox"/> Caucasian <input type="checkbox"/> Hispanic <input type="checkbox"/> Mediterranean
Phone: _____ E-mail: _____	<input type="checkbox"/> Native American <input type="checkbox"/> Other _____
REFERRING PHYSICIAN INFORMATION	
Name (Last, First, MI.): _____ Provider NPI# _____ Institution Name: _____	
Address: _____ City: _____ State: _____ Zip: _____	
Phone: _____ Fax: _____ E-mail: _____	
Genetic Counselor/Additional Recipient: _____ Phone/Fax/Email: _____	
Preferred Method of reporting: <input type="checkbox"/> Website Portal <input type="checkbox"/> Fax <input type="checkbox"/> Mail <input type="checkbox"/> Phone	Location ID: _____
SAMPLE INFORMATION	CLINICAL INFORMATION
Date Collected: _____	Clinical Indications: _____
Date Received: _____ (Lab Use Only)	ICD-10 codes: _____
Collected By: _____ Volume: _____	ICD-10 codes: _____
Sample Type: <input type="checkbox"/> Blood (EDTA purple-top tube) <input type="checkbox"/> Saliva <input type="checkbox"/> DNA	ICD-10 codes: _____
Please check all of the following situations that apply:	
<input type="checkbox"/> Patient has had bone marrow transplant	<input type="checkbox"/> Patient has had transfusion within the past 30 days
<input type="checkbox"/> Patient has had bone marrow transplant	<input type="checkbox"/> Patient or immediate family member is pregnant
BILLING INFORMATION	
<input type="checkbox"/> INSTITUTIONAL BILLING Institution Name and Contact: _____	
<input type="checkbox"/> MEDICARE/MEDICAID Medicare/Medicaid No. _____ State: _____	
<input type="checkbox"/> INSURANCE BILLING Please include a copy of insurance card(s) both front and back for billing purposes	
Policyholder Name _____ DOB (MM/DD/YY) _____ Phone No. _____	
Insurance Co. _____ Member ID _____ Group No. _____	
<input type="checkbox"/> SELF PAYMENT (Invoice for payment will be issued upon receipt of sample. Please completely fill out patient's address to avoid delay of	
Patient /Guardian Acknowledgement for Financial Responsibility	
I acknowledge that the information provided by me is true to the best of my knowledge. I hereby authorize my insurance benefits to be paid directly to Breakthrough Genomics and authorize them to release medical information concerning my testing to my insurer. I understand that I am financially responsible for any amounts not covered by my insurer for this test order. I also fully understand that I am legally responsible for sending Breakthrough Genomics any money received from my health insurance company for the performance of this genetic test. Failing to do so will result in my account being sent to collection.	
Patient/Guardian's Name: _____ Patient/Guardian's Signature: _____ Date: _____	

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STATEMENT OF MEDICAL NECESSITY

Informed Consent and Statement of Medical Necessity

I have supplied information to the patient/guardian regarding genetic testing and the patient/guardian has given consent for genetic testing to be performed. I further confirm that this test is medically necessary for the diagnosis or detection of a disease, illness, impairment, symptom, syndrome or disorder, and the results will be used in the medical management and treatment decisions for the patient. I confirm that the person listed in the Ordering Physician space above is authorized by law to order the test(s) requested herein.

Physician's Name: _____ Physician's Signature: _____ Date: _____

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TEST CATALOGUE

Genetic Testing

- | | |
|---|--|
| <input type="checkbox"/> Comprehensive Hereditary Cancer Panel | <input type="checkbox"/> Hereditary Melanoma and Skin Cancer Panel |
| <input type="checkbox"/> Hereditary Breast and Gynecological Cancer Panel | <input type="checkbox"/> Hereditary Pancreatic Cancer Core Panel |
| <input type="checkbox"/> Hereditary Breast Cancer High Risk Panel | <input type="checkbox"/> Hereditary Pancreatic Cancer Panel |
| <input type="checkbox"/> Hereditary Colorectal Cancer Panel | <input type="checkbox"/> Hereditary Paraganglioma-Pheochromocytoma Panel |
| <input type="checkbox"/> Hereditary Endocrine Cancer Panel | <input type="checkbox"/> Hereditary Pediatric Cancer Panel |
| <input type="checkbox"/> Hereditary Gastrointestinal Cancer Panel | <input type="checkbox"/> Hereditary Renal Cancer Panel |
| <input type="checkbox"/> Hereditary Leukemia Panel | <input type="checkbox"/> Neurofibromatosis Panel |
| <input type="checkbox"/> Hereditary Lung Cancer Panel | <input type="checkbox"/> Tuberous Sclerosis Panel |
| | <input type="checkbox"/> Xeroderma Pigmentosum Panel |

CLINICAL AND FAMILY HISTORY (Clinical Note Must Be Attached)

Previous clinical/genetic testing (of patient's or family members):

Test: _____ Result: _____

Test: _____ Result: _____

Clinical Symptoms of patient or family members:

Patient /Family member <u>i.e. Father</u>	Symptoms/Diagnosis (please specify age of diagnosis after each diagnosis)
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

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INFORMED CONSENT FOR GENETIC TESTING

First Name: _____

Last Name: _____

DOB (MM/DD/YYYY): _____

I understand that my health care provider has ordered the following genetic testing for {me/my child}:

This is a voluntary test to identify gene mutation associated with hereditary disease and health risks and you may wish to seek genetic counseling prior to signing this form. Read this form carefully before making your decision about testing.

PURPOSE

I am interested in obtaining a genetic test by submitting a biological sample of my own (blood, saliva, or other tissue). The purpose of this molecular genetic test is to ascertain if I am, or my child is, carrying mutation(s) predisposing to or causing disease or elevated health risks. The biological sample submitted is required for isolation and purification of DNA and molecular genetic testing by next generation sequence analysis of genes associated with hereditary health risks.

THE FOLLOWING POINTS WERE EXPLAINED AND I UNDERSTAND THAT:

1. Due to the complexity of DNA based testing and the implications of the results, these results will be reported only through my designated physician(s) or genetic counselor (where allowed) and that I must contact my provider to obtain the results of the test. The test results, in addition, could be released to all who, by law, may have access to such data.
2. DNA-based studies performed are specific to the condition indicated above. The results should be evaluated in the context of personal and family health history, the results of physical examination, laboratory and hospital test, and clinical impression of my healthcare provider. I understand that possible result outcomes include positive, negative, and uncertain.
3. If results of the tests are uncertain (in the case of variants of unknown clinical significance), meaning that there is not enough information to determine whether this change is associated with an increased risk after thorough search of current literature and databases.
4. Unexpected results may be revealed from this test in rare instances. This test is designed to detect changes in genes that predispose a person to a certain health condition; however, it can sometimes uncover genetic conditions in a family unrelated to the targeted disease risks. Results also have the potential to reveal unexpected biological relationships, such as a different biological parent.
5. It is the responsibility of the referring physician or health care provider to understand the specific utility and limitations of the testing ordered, and to educate the patient regarding these limitations. While this test is designed to identify most detectable mutations in the genes analyzed, it is still possible there are mutations that this testing technology is unable to detect. In addition, there may be other genes associated with disease susceptibility that are not included on this panel or that are not known at this time.
6. The molecular genetic test occasionally may not generate results and that an additional blood, saliva, or tissue sample may be needed to obtain interpretable results.
7. Inaccurate results, though rare, may occur for the following reasons: sample mix-up, samples unavailable from critical family members, maternal contamination of prenatal samples, inaccurate reporting of family relationships, or technical problems, but not limited to these.
8. The genetic tests results have implications for blood relatives. In consultation with an appropriate healthcare provider, I may wish to discuss sharing the test results with certain blood relatives who may be at risk.

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USE OF SPECIMENS FOR RESEARCH

After testing is completed, I understand that leftover blood, saliva, or tissue specimens may be disposed of or retained indefinitely for de-identified research, test validation, and/or education as long as my privacy is maintained. I understand that no compensation will be given for using the specimens submitted. I understand that I may refuse to submit my specimen for use in this way and may withdraw my consent at any time by contacting the laboratory. I understand that my refusal to consent to medical research will not affect my results. Indicate consent or denial below. If neither box is marked, consent is implied.

Consent to the use of my sample for anonymous research:

Yes No

OPT OUT REQUEST

I choose to opt out of receiving test results in the following disease categories:

- Adult onset cancer
- Carrier screening
- Adult onset neurological diseases

Other _____

RECOMMENDATIONS

I understand that due to the dynamics of medical genetics field, there continues to be new information and data. It is recommended that I keep in contact with my healthcare provider, annually, to learn of any new developments in medical genetics and to provide any updates to my personal or family history which may affect my disease susceptibility risks.

PATIENT/GUARDIAN CONSENT STATEMENT

By signing below, I, the patient or Guardian having the test performed, acknowledge that:

I have read or have had read to me all of the above statements and understand the information above and have had the opportunity to ask questions. I understand the procedure, the risks, benefits, limitations and the alternatives associated with this test. I can request a copy of this consent form.

Patient Name: _____ Date: _____

Patient Signature: _____

Guardian Name: _____ Date: _____

Guardian Signature: _____