BREAKTHROUGH GENOMICS

Breakthrough Genomics
2 Hughes, Suite 100
Irvine, CA 92618
Phone: (949) 381-3794
info@btgenomics.com www.btgenomics.com

GENERAL GENETIC TEST REQUISITION FORM

PATIENT INFORMATION

Patient Last Name:_____ Patient First Name:_____ MI:_____

Date of Birth (MM/DD/YY):_____ Sex ☐ Male ☐ Female ☐ Unknown

Address:_____

City:_____ State:_____ Zip:_____

Phone:_____ E-mail:_____

Ethnic Background (check all that apply):

☐ African American ☐ Asian/Pacific Islander
☐ Caucasian ☐ Hispanic ☐ Mediterranean
☐ Native American ☐ 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: ☐ Website Portal ☐ Fax ☐ Mail ☐ Phone

Location ID:_____

SAMPLE INFORMATION

Date Collected:_____

Date Received:_____(Lab Use Only)

Collected By:_____ Volume:_____

Sample Type: ☐ Blood (EDTA purple-top tube) ☐ Saliva ☐ DNA

CLINICAL INFORMATION

Clinical Indications:_____

ICD-10 codes:_____

Please check all of the following situations that apply:

☐ Patient has had bone marrow transplant

☐ Patient has had transfusion within the past 30 days

☐ Patient or immediate family member is pregnant

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:_____

TEST CATALOGUE

Genetic Testing

☐ 2001 Clinical Whole Exome Sequencing
☐ 2005 Clinical Whole Genome Sequencing
☐ 2021 All Cancer Panel (94 genes)
☐ 2022 Spinal Muscular Atrophy (SMA) Copy Number Analysis

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INSURANCE BILLING					
Attach Front and Back of Insurance Cards, ABN, Medical Criteria Form					
PLEASE ATTACH INSURANCE CARDS FOR BILLING	ICD-10 VALID CODE	REFERRAL/PRIOR AUTH	BENEFITS ID #		
By signing above, the patient or insured authorizes Breakthrough Genomics to release medical information concerning the test to the assigned insurance company					
INSURANCE PLAN	NAME OF INSURED	RELATION TO PATIENT	DATE OF BIRTH (MM/DD/YYYY)		
SECONDARY INSURANCE ID	INSURANCE NAME	STATE	GROUP	INSURANCE PHONE #	
INSURANCE PLAN	NAME OF INSURED	RELATION TO PATIENT	DATE OF BIRTH (MM/DD/YYYY)		

INSTITUTIONAL BILLING				
INSTITUTION/PRACTICE NAME				
ATTENTION TO				
ADDRESS	CITY	STATE/PROVINCE	POSTAL CODE	COUNTRY
PHONE		FAX/EMAIL		

SELF PAY			
◉ Use patient information above for billing ○ Use information below for billing		By signing above, the patient or payor authorizes Breakthrough Genomics to contact them directly and use the provided billing instructions to bill the indicated method.	
PAYOR LAST NAME		PAYOR FIRST NAME	
ADDRESS			
CITY	STATE/PROVINCE	POSTAL CODE	COUNTRY
PHONE		FAX/EMAIL	

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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 i.e. Father	Symptoms/Diagnosis (please specify age of diagnosis after each diagnosis)

FAMILY PEDIGREE

Family history:

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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 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

RECOMMENDATIONS

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

Patient Name:_____ Date:_____

Patient Signature:_____