Breakthrough Genomics

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

CARDIOLOGY GENETIC TEST REQUISITION FORM

PATIENT INFORMATION

Patient Last Name:_____ Patient First Name:_____ MI_____

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

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

BILLING INFORMATION

☐ INSTITUTIONAL BILLING Institution Name and Contact: _____

☐ MEDICARE/MEDICAID Medicare/Medicaid No._____ State: _____

☐ 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. _____

☐ 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

- ☐ Aorta Panel
- ☐ Arrhythmia Panel
- ☐ Arrhythmogenic Right Ventricular Cardiomyopathy (ARVC) Panel
- ☐ Atrial Fibrillation Panel
- ☐ Brugada Syndrome Panel
- ☐ Cardiomyopathy Panel
- ☐ Catecholaminergic Polymorphic Ventricular Tachycardia (CPVT) Panel
- ☐ Comprehensive Cardiology Panel
- ☐ Congenital Structural Heart Disease Panel
- ☐ Dilated Cardiomyopathy (DCM) Panel
- ☐ Ehlers-Danlos Syndrome Panel
- ☐ Hereditary Hemorrhagic Telangiectasia (HHT) Panel
- ☐ Heterotaxy and Situs Inversus Panel
- ☐ Hyperlipidemia Core Panel
- ☐ Hyperlipidemia Panel
- ☐ Hypertrophic Cardiomyopathy (HCM) Panel
- ☐ Left Ventricular Non-Compaction Cardiomyopathy (LVNC) Panel
- ☐ Liddle Syndrome Panel
- ☐ Long QT Syndrome (LQTS) Panel
- ☐ Marfan Syndrome Panel
- ☐ Noonan Syndrome Panel
- ☐ Pulmonary Artery Hypertension (PAH) Panel
- ☐ Short QT Syndrome (SQTS) 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 i.e. Father	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 compensationwill 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 opportunityto 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: _____

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Cardio Related Panels with Payable ICDs	
Panel Name	**ICDs**
Aorta Panel	I35.0 - Nonrheumatic aortic (valve) stenosis I35.1 - Nonrheumatic aortic (valve) insufficiency I35.2 - Nonrheumatic aortic (valve) stenosis with insufficiency I35.8 - Other nonrheumatic aortic valve disorders I35.9 - Nonrheumatic aortic valve disorder, unspecified
Arrhythmia Panel	I49.01 - Ventricular fibrillation I49.02 - Ventricular flutter I49.1 - Atrial premature depolarization I49.2 - Junctional premature depolarization I49.3 - Ventricular premature depolarization I49.40 - Unspecified premature depolarization I49.49 - Other premature depolarization I49.5 - Sick sinus syndrome I49.8 - Other specified cardiac arrhythmias I49.9 - Cardiac arrhythmia, unspecified R00.0 - Tachycardia, unspecified R00.1 - Bradycardia, unspecified R00.2 - Palpitations R00.8 - Other abnormalities of heart beat R00.9 - Unspecified abnormalities of heart beat
Arrhythmogenic Right Ventricular Cardiomyopathy (ARVC) Panel	I42.0 - Dilated cardiomyopathy I42.1 - Obstructive hypertrophic cardiomyopathy I42.3 - Endomyocardial (eosinophilic) disease I42.8 - Other cardiomyopathies
Atrial Fibrillation Panel	I48.0 - Paroxysmal atrial fibrillation I48.1 - Persistent atrial fibrillation I48.2 - Chronic atrial fibrillation I48.3 - Typical atrial flutter I48.4 - Atypical atrial flutter I48.91 - Unspecified atrial fibrillation I48.92 - Unspecified atrial flutter
Brugada Syndrome Panel	I49.01 - Ventricular fibrillation I49.02 - Ventricular flutter I49.1 - Atrial premature depolarization I49.2 - Junctional premature depolarization I49.3 - Ventricular premature depolarization I49.40 - Unspecified premature depolarization I49.49 - Other premature depolarization I49.5 - Sick sinus syndrome I49.8 - Other specified cardiac arrhythmias I49.9 - Cardiac arrhythmia, unspecified R00.0 - Tachycardia, unspecified R00.1 - Bradycardia, unspecified

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	R00.2 - Palpitations R00.8 - Other abnormalities of heart beat R00.9 - Unspecified abnormalities of heart beat

Cardiomyopathy Panel	I42.0 - Dilated cardiomyopathy I42.1 - Obstructive hypertrophic cardiomyopathy I42.3 - Endomyocardial (eosinophilic) disease I42.4 - Endocardial fibroelastosis I42.5 - Other restrictive cardiomyopathy I42.6 - Alcoholic cardiomyopathy I42.7 - Cardiomyopathy due to drug and external agent I42.8 - Other cardiomyopathies

Catecholaminergic Polymorphic Ventricular Tachycardia (CPVT) Panel	I47.2 - Ventricular tachycardia

Comprehensive Cardiology Panel	I25.10 - Atherosclerotic heart disease of native coronary artery without angina pectoris I48.91 - Atrial Fibrillation I50.9 - Congestive Heart Failure I63.9 - CVA I63.9 - Stroke I65.23 - Carotid Artery Occlusion, Bilateral I65.23 - Carotid Artery Stenosis, Bilateral I65.29 - Carotid Artery Occlusion I65.29 - Carotid Artery Stenosis I67.2 - Cerebral Atherosclerosis I67.9 - Ischaemic Cerebrovascular Disease I73.9 - Peripheral Vascular Disease I20.9 - Angina Pectoris,NOS I21.09 - Myocardial Infarction,Acute,Anterior I21.3 - Myocardial infarction, acute unspecified I25.10 - ASHD Coronary Artery I25.2 - Old Myocardial Infarction I25.84 - Coronary Atherosclerosis due to calcified Coronary Lesion I25.9 - Chronic Ischaemic Heart Disease I11.0 - Malignant Hypertension Heart Disease with Heart Failure I11.9 - Benign Hypertension Heart Disease without Heart Failure

Congenital Structural Heart Disease Panel	Q24.0 - Dextrocardia Q24.1 - Levocardia Q24.2 - Cor triatriatum Q24.3 - Pulmonary infundibular stenosis Q24.4 - Congenital subaortic stenosis Q24.5 - Malformation of coronary vessels Q24.6 - Congenital heart block Q24.7 - Other specified congenital malformations of heart Q24.8 - Other specified congenital malformations of heart Q24.9 - Congenital malformation of heart, unspecified

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Dilated Cardiomyopathy (DCM) Panel	I42.0 - Dilated cardiomyopathy
Ehlers-Danlos Syndrome Panel	Q79.60 - Ehlers-Danlos syndrome, unspecified
Hereditary Hemorrhagic Telangiectasia (HHT) Panel	I78. 0 - Hereditary hemorrhagic telangiectasia
Heterotaxy and Situs Inversus Panel	Q89.3 - Situs inversus Q24.8 - Other specified congenital malformations of heart
Hyperlipidemia Core Panel	E78.0 - Pure hypercholesterolemia E78.00 - Pure hypercholesterolemia, unspecified E78.01 - Familial hypercholesterolemia E78.1 - Pure hyperglyceridemia E78.2 - Mixed hyperlipidemia E78.3 - Hyperchylomicronemia E78.4 - Other hyperlipidemia E78.41 - Elevated Lipoprotein(a) E78.49 - Other hyperlipidemia E78.5 - Hyperlipidemia, unspecified E78.6 - Lipoprotein deficiency E78.70 - Disorder of bile acid and cholesterol metabolism E78.71 - Barth syndrome E78.72 - Smith-Lemli-Opitz syndrome E78.79 - Other disorders of bile acid and cholesterol E78.81 - Lipoid dermatoarthritis E78.89 - Other lipoprotein metabolism disorders E78.9 - Disorder of lipoprotein metabolism , unspecified
Hyperlipidemia Panel	E78.0 - Pure hypercholesterolemia E78.00 - Pure hypercholesterolemia, unspecified E78.01 - Familial hypercholesterolemia E78.1 - Pure hyperglyceridemia E78.2 - Mixed hyperlipidemia E78.3 - Hyperchylomicronemia E78.4 - Other hyperlipidemia E78.41 - Elevated Lipoprotein(a) E78.49 - Other hyperlipidemia E78.5 - Hyperlipidemia, unspecified E78.6 - Lipoprotein deficiency E78.70 - Disorder of bile acid and cholesterol metabolism E78.71 - Barth syndrome E78.72 - Smith-Lemli-Opitz syndrome E78.79 - Other disorders of bile acid and cholesterol E78.81 - Lipoid dermatoarthritis E78.89 - Other lipoprotein metabolism disorders E78.9 - Disorder of lipoprotein metabolism , unspecified
Hypertrophic Cardiomyopathy (HCM) Panel	I42.1 - Obstructive hypertrophic cardiomyopathy I42.2 - Other hypertrophic cardiomyopathy

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Left Ventricular Non-Compaction Cardiomyopathy (LVNC) Panel	I42.8 - Other cardiomyopathies
Liddle Syndrome Panel	I15.1 - Hypertension secondary to other renal disorders
Long QT Syndrome (LQTS) Panel	I45.81 - Long QT syndrome
Marfan Syndrome Panel	Q87.40 - Marfan's syndrome, unspecified
Noonan Syndrome Panel	Q87.19 - Other congenital malformation syndromes predominantly associated with short stature
Pulmonary Artery Hypertension (PAH) Panel	I27.21 - Secondary pulmonary arterial hypertension
Short QT Syndrome (SQTS) Panel	I45.81 - Long QT syndrome