



Test Requisition and Statement of Medical Necessity

PATIENT INFORMATION

Name: Last _____ First _____ MI _____
Address: Street _____ Apt # _____
City _____ State _____ Zip _____
Telephone: Daytime _____ Evening _____
DOB: MM/DD/YY _____ SSN _____
 Male Female Ethnicity _____

REFERRING PHYSICIAN/ACCOUNT INFORMATION

Name: Last _____ First _____ Degree _____
Address: Street _____ Suite # _____
City _____ State _____ Zip _____
Institution/Hospital _____
Telephone _____ Fax _____
Email _____
NPI # _____ Group NPI # _____
Office Contact _____

ADDITIONAL PHYSICIAN TO RECEIVE TEST RESULTS

Name: Last _____ First _____ Degree _____
Address: Street _____ Suite # _____
City _____ State _____ Zip _____
Institution/Hospital _____
Telephone _____ Fax _____
Email _____

BILLING INFORMATION

BILL: Facility Account Patient Insurance Self-pay Government (Canada)

For Facility Accounts

NAME OF FACILITY ACCOUNT _____

For Patient Insurance

PRIMARY INSURANCE: Please provide a legible copy of both sides of the insurance card.

SECONDARY INSURANCE: You may submit secondary insurance information when applicable. Please provide a legible copy of both sides of the insurance card.

PGxHealth will contact the patient (or legal guardian) with insurance benefit information. No testing is done without the patient's or legal guardian's permission.

Primary Insurance Company _____
Address: Street _____
City _____ State _____ Zip _____
Telephone _____
Policy Holder/Subscriber _____
Relationship to Patient _____
Policy Holder's DOB _____ Policy Holder's SSN _____
Policy # _____
Group # (if applicable) _____
Name of Employer _____

PATIENT PAYMENT: Mail payments to: PGxHealth, PO Box 83236, Woburn, MA 01813-3236

For Self-pay

PGxHealth accepts the following credit cards: Visa, MasterCard, AMEX and Discover

Yes, I plan on using my credit card to pay for testing. Please contact me directly.

REQUIRED DIAGNOSIS /ICD-9 CODE(S)

Diagnosis/ICD-9 Code(s) _____

TEST SELECTION

If ordering multiple tests, please signify order of completion. Your office will be contacted with each test's result prior to proceeding with additional testing. Each test requires two 4 mL purple-top EDTA tubes of blood.

- LQTS Test:** (KCNQ1, KCNH2, KCNE1, KCNE2, SCN5A, KCNJ2*, CACNA1C*, CAV3, SCN4B, AKAP9*, SNTA1)
- CPVT Test:** (RYR2*, KCNJ2*)
- BrS Test:** (SCN5A)
- HCM Test:** (MYH7, MYBPC3, TNNT2, TNNI3, TPM1, MYL2, TNNC1, MYL3, ACTC, GLA, LAMP2, PRKAG2)
- ARVC Test:** (DSP, PKP2, DSG2, DSC2, TMEM43)
- DCM Test:** (LMNA, ANKRD1, TNNC1, SCN5A, TPM1, MYBPC3, ACT1, LDB3, PLN, MYH7, TNNT2, TNNI3)
- Family Specific Test**
- Research Confirmation:** (Please contact PGxHealth Customer Service for instructions)

For Family Specific Test Only

Index Code: GPI- _____

Index Case is the patient of reference for a family

Name of Index Case _____

Relationship to the Index Case _____

* See the FAMILION technical specification sheet for coverage areas.

CLINICAL HISTORY (Check All That Apply)

- | | |
|---|--|
| SUSPECTED CLINICAL DIAGNOSIS: | PRESENTING SIGNS/SYMPTOMS: |
| <input type="checkbox"/> Long QT Syndrome (LQTS) | <input type="checkbox"/> Chest pain <input type="checkbox"/> Heart murmur |
| <input type="checkbox"/> QTc (LQTS only) = _____ ms | <input type="checkbox"/> Cardiac Arrest <input type="checkbox"/> Sudden Cardiac Death (Deceased) |
| <input type="checkbox"/> Deafness (LQTS only) | <input type="checkbox"/> Arrhythmias |
| <input type="checkbox"/> Brugada Syndrome | <input type="checkbox"/> Abnormal ECG Family History: |
| <input type="checkbox"/> CPVT | <input type="checkbox"/> Syncope <input type="checkbox"/> Sudden Cardiac Death |
| <input type="checkbox"/> HCM | <input type="checkbox"/> Seizures <input type="checkbox"/> Inherited Cardiac Disease |
| <input type="checkbox"/> ARVC | <input type="checkbox"/> Dyspnea |
| <input type="checkbox"/> DCM | <input type="checkbox"/> Left ventricular hypertrophy |
| | <input type="checkbox"/> Dilation of right or left ventricle |
| | <input type="checkbox"/> Fatty infiltration of right or left ventricle |

REQUIRED PATIENT/PHYSICIAN SIGNATURES

PATIENT/RESPONSIBLE PARTY SIGNATURE TO AUTHORIZE TESTING AND VERIFY INFORMED CONSENT (REQUIRED):

I authorize my physician and other medical personnel to provide information to PGxHealth concerning my medical history, and I authorize PGxHealth to disclose the results of my testing and any related health and personal information to my physician. I have read the Informed Consent for FAMILION testing and understand its contents. I have had the opportunity to ask questions about this form and have had any questions answered.

Patient or Legal Guardian (REQUIRED)

Signature _____ Date _____ Please Sign & Date

Print Name _____

Relationship _____

PHYSICIAN SIGNATURE TO AUTHORIZE TESTING AND STATEMENT OF MEDICAL NECESSITY (REQUIRED):

I certify that the Informed Consent has been discussed with the patient or an individual legally authorized to do so on the patient's behalf (and that such form is on file), and that I obtained any other consent from the patient that is required under the laws of my state in order to perform a genetic test on a specimen. I further certify that the test ordered is medically necessary. The results of this test will be used in the medical management of the patient and/or genetic counseling of the patient and their family. (Note: test requests without a signature will not be processed.)

Referring physician to authorize testing (REQUIRED):

Signature _____ Date _____ Please Sign & Date

Informed Consent for *FAMILION*® Testing

For the presence of genetic variants detected by DNA sequencing that may be associated with cardiac ion channel mutations, which are found in conditions such as Long QT Syndrome (LQTS), Brugada Syndrome (BrS) and Catecholaminergic Polymorphic Ventricular Tachycardia (CPVT) or cardiomyopathies such as Hypertrophic Cardiomyopathy (HCM), Arrhythmogenic Right Ventricular Cardiomyopathy (ARVC) and Dilated Cardiomyopathy (DCM). I have discussed the benefits, risks and limitations of this testing with my healthcare provider and/or a genetic counselor and I have had my questions answered. By signing this form, I give my consent to have my blood, DNA, or tissue sample and relevant clinical information sent to PGxHealth, for *FAMILION* testing. I also authorize PGxHealth to disclose the test results to their authorized personnel and the ordering physician(s).

I UNDERSTAND THE FOLLOWING BENEFITS, RISKS AND LIMITATIONS:

1. While genetic testing is a valuable tool, it may not always give a definite answer about the genetic status of an individual. Genetic testing normally gives precise information; possible sources of error include but are not limited to sample misidentification and sample contamination.
2. The results of this test may indicate that you are predisposed to or have LQTS, CPVT, BrS, HCM, ARVC, DCM or a related condition. Follow-up genetic counseling is available to address any questions you may have regarding the results. Your physician may recommend additional testing or you may also wish to consider further independent testing. You can discuss this further with your healthcare provider.
3. Your blood or tissue sample and any DNA will be destroyed no more than 60 days after your results are final. No tests other than those authorized will be performed on the sample. If we are unable to confirm that you wish to test or you inform us that you choose not to proceed with testing, your sample will be destroyed within 60 days after our last contact with you.
4. In rare circumstances, the laboratory may have difficulties analyzing your sample and a second sample may be requested.
5. Genetic testing may involve emotional stress. The Genetic Information Nondiscrimination Act (GINA) of 2008 prohibits health insurance plans and employers from some discrimination based on genetic information, including the results of genetic testing. However, such genetic testing may result in life insurance, disability insurance and/or long-term care insurance discrimination that is not prohibited by law.
6. If other members of my family have had the same or similar tests, the results of this testing may suggest previously unrecognized biological relationships, such as non-paternity.
7. The results of this test will be kept confidential and will be released only to the physician(s) ordering the test or other persons authorized by you, in writing, unless otherwise required by Federal and state law.
8. By signing this consent, you give PGxHealth permission to retain the genetic information generated by this test and to contact your physician if PGxHealth learns new information about the genetic variants detected by this test that affects your reported test results. PGxHealth will make reasonable efforts to contact your physician in these instances.
9. In the interest of advancing the understanding of these heart conditions, summary results from this test may be presented, for example at meetings, in publications, or on the Internet; however, no information that can identify you will ever be disclosed, unless authorized in writing by you or required by law.
10. The results of this test are not intended to be used as the sole means for diagnosis or management decisions.
11. There will be a fee for this genetic testing and you will be responsible for payment after the testing has begun, even if you decide not to receive results. Testing will only begin after we receive your blood, DNA or tissue sample and after payment has been authorized and you have indicated to PGxHealth that you wish to proceed.

For Patient or Responsible Party Selecting the Patient Insurance Billing Option

12. I have selected the patient insurance billing option and hereby authorize PGxHealth to bill my insurance carrier. Further, I authorize PGxHealth to disclose to my insurance carrier the information on this form and any accompanying documentation provided by my healthcare provider. I authorize my health plan or insurance carrier, and other third parties involved in the administration of my plan, to disclose to PGxHealth information concerning my plan, including benefits, coverage limitations, and payments made for services.
13. I hereby assign and authorize payment directly to PGxHealth of any benefits for the services provided. I understand that my insurance may not cover these services, or may only pay up to usual and customary rates, and that I am ultimately responsible for all costs of this test and costs of collections, including attorney fees, court costs, filing fees, and late payment fees, except where my liability is limited by contract or applicable state or Federal law.

NOTE:

Genetic testing on children less than 18 years of age requires that the ordering physician obtain an informed consent from a parent or legal guardian.