TRANSGENOMIC • FIVE SCIENCE PARK • NEW HAVEN, CT 06511
Patient Services: 1.877.274.9432 • Fax: 203.786.3418

Test Requisition and Statement of Medical Necessity

WWW.FAMILION.COM

Date of Blood Sample Collection: __ __ / __ __ / __ __ __ __

Affix Bar Code Sticker Here

PATIENT INFORMATION

Name: Last ______ First ______ MI ______

Address: Street ______ Apt # ______

City ______ State ______ Zip ______

Telephone: Daytime ______ Evening ______

Email (optional) ______

DOB: MM/DD/YY ______ Gender: ☐ Male ☐ Female

Ethnicity ______ Patient Status: ☐ Inpatient ☐ Outpatient

ORDERING PHYSICIAN/ACCOUNT INFORMATION

Name: Last ______ First ______ Degree ______

Address: Street ______ Suite # ______

City ______ State ______ Zip ______

Institution/Hospital ______

Telephone ______ Fax ______

Email ______

NPI # ______ Group NPI # ______

Office Contact ______

ADDITIONAL HEALTHCARE PROFESSIONAL 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**

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.

Transgenomic 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 # ______

Group # (if applicable) ______

Name of Employer ______

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

ONLINE PAYMENT: www.sbgpayments.net/payments/familion.com/payment.php

For Self-pay

Transgenomic 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.

TBIO Part Number: 482300-04 November 2011

REQUIRED DIAGNOSIS /ICD-9 CODE(S)

Diagnosis/ICD-9 Code(s) ______

TEST SELECTION*

Supply one filled 4 mL purple-top ETDA tube of blood.
If ordering multiple tests, please signify order of completion next to test selections.

______ ☐ **LQTS Test:** *(KCNQ1, KCNH2, KCNE1, KCNE2, ANK2, SCN5A, KCNJ2, CACNA1C, CAV3, SCN4B, AKAP9, SNTA1, KCNJ5)*

______ ☐ **LQTS Large Deletion/Duplication Test:** *(KCNQ1, KCNH2, KCNE1, KCNE2)*

______ ☐ **CPVT Test:** *(RYR2, KCNJ2, CASQ2, ANK2)*

______ ☐ **BrS/J-Wave Test:** *(SCN5A, GPD1L, CACNA1C, CACNB2, SCN1B, KCNE3, SCN3B KCND3, KCNJ8)*

______ ☐ **Familial AF Test:** *(GJA5, KCNA5, KCNE1L, KCNE2, KCNJ2, KCNQ1, NPPA, SCN5A)*

______ ☐ **SQTS Test:** *(KCNH2, KCNQ1, KCNJ2)*

______ ☐ **Timothy Syndrome Test:** *(CACNA1C)*

______ ☐ **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, ACTC, LDB3, PLN, MYH7, TNNT2, TNNI3, TAZ)*

______ ☐ **CD-DCM Test:** *(LMNA, SCN5A)*

______ ☐ **LVNC Test:** *(MYH7, LDB3, ACTC, TAZ, TNNT2, MYBPC3, LMNA)*

______ ☐ **Marfan/TAAD Test:** *(FBN1, TGFBR1, TGFBR2, ACTA2)*

______ ☐ **Marfan Large Deletion/Duplication Test:** *(FBN1)*

☐ **Family Specific Testing** **Type** ______

☐ **Genetic Testing Confirmation:** (Please contact Transgenomic Patient Service for instructions)

For Family Specific Test Only

Family Specific Code: GPI-__ __ __ __ __ __ __ __ __ __

A family specific code is generated for each Index Case, which is the person of reference in the family

Name of Index Case ______

Relationship to the Index Case ______

* *See the FAMILION Technical Specifications for coverage areas (www.familion.com).*

CLINICAL HISTORY (Check All That Apply)

SUSPECTED CLINICAL DIAGNOSIS:

☐ Long QT Syndrome (LQTS)
QTc (LQTS only) = ______ ms
☐ Deafness (LQTS only)
☐ Brugada/J-Wave Syndrome
☐ CPVT
☐ HCM
☐ ARVC
☐ DCM
☐ Conduction Disease
☐ LVNC
☐ Marfan/TAAD
☐ Other______

PRESENTING SIGNS/SYMPTOMS:

☐ Chest pain
☐ Cardiac Arrest
☐ Arrhythmias
☐ Abnormal ECG
☐ Syncope
☐ Seizures
☐ Dyspnea
☐ Left ventricular hypertrophy
☐ Dilation of right or left ventricle
☐ Fatty infiltration of right or left ventricle
☐ Trabeculation
☐ Aortic Dissection
☐ Heart murmur
☐ Sudden Cardiac Death (Deceased)

Family History:

☐ Sudden Cardiac Death
☐ Inherited Cardiac Disease

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 Transgenomic concerning my medical history, and I authorize Transgenomic 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 ______

HEALTHCARE PROFESSIONAL SIGNATURE TO AUTHORIZE TESTING AND STATEMENT OF MEDICAL NECESSITY:

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.

Referring healthcare professional to authorize testing:

Signature ______ **Date** ______ Please Sign & Date

Print Name ______

Internal Use Only

Date Received ______ Tech ______

Tracking # ______

FAMILION®
Genetic Tests for Inherited Cardiac Syndromes

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Informed Consent for Genetic Testing

I have discussed the benefits, risks and limitations of genetic testing with my healthcare provider and 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 Transgenomic for testing. I also authorize Transgenomic to disclose the test results to the ordering physician and any other provider I designate.

I UNDERSTAND THE FOLLOWING BENEFITS, RISKS AND LIMITATIONS:

1. The results of this test may indicate that you are predisposed to or have an inherited condition. Follow-up genetic counseling is available to address any questions you may have regarding the results. Your physician may recommend additional testing. You can discuss this further with your healthcare provider.

2. While genetic testing is a valuable tool, it may not always give a definite answer about the genetic status of an individual. While some genetic variants are known to cause disease and others are benign, a proportion of genetic testing results are of uncertain significance.

3. Your sample will not be banked. Your blood or tissue sample and any DNA will be destroyed no more than 60 days after your results are final unless reserved for quality control purposes. Precious samples, such as muscle biopsies or post-mortem specimens, will be returned upon request. No tests other than those authorized will be performed on your sample. If you have notified us that you do not wish to proceed with testing, your sample will be destroyed within 60 days. If we are unable to confirm that you wish to test, your sample will be destroyed within 6 months 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. Genetic testing normally gives accurate information; rare sources of error include but are not limited to sample misidentification and sample contamination.

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. The results of this test are not intended to be used as the sole means for diagnosis or management decisions.

9. By signing this consent, you give Transgenomic permission to retain the genetic information generated by this test and to contact your physician if Transgenomic learns new information about the genetic variants detected by this test that affects your reported test results. Transgenomic will make reasonable efforts to contact your physician in these instances. It is the responsibility of the patient to maintain current contact information with the healthcare provider so that the patient may be advised of any changes to their test results.

10. In the interest of advancing the understanding of these 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.

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 Transgenomic 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 Transgenomic to bill my insurance carrier. Further, I authorize Transgenomic 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 Transgenomic information concerning my plan, including benefits, coverage limitations, and payments made for services.

13. I hereby assign and authorize payment directly to Transgenomic 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.