**SECURE HEALTH**

## FAX - TIME SENSITIVE
## PLEASE RETURN TO SECURE HEALTH FAX: 801-509-6879

**To:**
**Fax:**
**Phone:**
**Date:**
**Subject:**
**Comments: PATIENT REQUESTED**

Your patient _____, is requesting a hereditary cardiac screening due to concerns with their personal or family history. Secure Health would like to include you in the process because you are the patients primary care physician and can help in the implementation of the results of the test into the patient's existing care plan. **Please sign the attached requisition form, the physician authorization form, and the certificate of medical necessity. The results will be sent via fax or via online portal, depending on preference.**

Also, please note that the attached ICD-10 codes are typically associated with medical necessity for hereditary cardiac screenings, but do not guarantee
coverage for any genetic test. Providers are NOT required to use the attached examples. Secure Health and all associated companies do require ICD-10 codes that are:

1. Patient specific
2. Prove the medical necessity to support testing
3. Are billable to the highest specificity

Samples that are received without proper ICD-10 coding will be held for 30 days. After this period, if the correct ICD-10 codes are not included, the sample will be destroyed.

## With any questions, please contact Secure Health at (801) 477-0474

# COMPREHENSIVE CARDIOMYOPATHY NGS PANEL.

AccurateDX
Accurate diagnosis for better patient care

(210) 571 - 1300
422 W Nakoma Dr
San Antonio, TX 78216

## PATIENT INFORMATION

First Name: ----------
Last Name: ----------
DOB (MM/DD/YYYY) ----------
☐ Male ☐ Female
Address: ----------
City: ---------- State: ---------- Zip Code: ----------
Phone: ---------- E-mail: ----------

■ Ancestry:

| | | |
|---|---|---|
| ☐ Caucasian | ☐ African American | ☐ Asian |
| ☐ Middle Eastern | ☐ Eastern European | ☐ Northam European |
| ☐ Middle Eastern | ☐ Native American | ☐ Western European |
| ☐ Hispanic | ☐ Pacific Islander | ☐ Caribbean |
| ☐ Central/South American | ☐ Ashkenazi Jewish | ☐ Others: ---------- |

## PROVIDER INFORMATION

Clinic Name: ----------
Physician Name: ----------
NPI# ----------
Address: ----------
City: ---------- State: ---------- Zip Code: ----------
Phone: ---------- Fax: ----------
E-mail: ----------

## SPECIMEN COLLECTION

Specimen Type ☐ Buccal Swab
Date of Collection ---------- Time of Collection ☐ AM ☐ PM

## BILLING INFORMATION

BILL: ☐ **Insurance** ☐ **Medicaid** ☐ **Medicare**

| | | |
|---|---|---|
| ■ Bill Insurance | Pre-Authorization Number if Applicable | Patient Direct Pay |
| Primary Insurance | ID Number# | Group Number |
| Secondary Insurance | ID Number# | Group Number |
| Name of Person Insured | Relationship to Insured | Date of Birth (MM/DD/YYYY) |

## HEREDITARY CARDIAC CONDITIONS TEST SELECTION

☐ **CARDIAC PANEL – 129 GENES**

A2ML1, ABCC9, ACADVL, ACTC1, ACTN2, ADA2, AGL, AKAP9, ALMS1, ANK2, ANKRD1, BAG3, BRAF, CACNA1C, CACNB2, CALR3, CASQ2, CAV3, CAVIN4, CBL, CHRM2, CPT2, CRYAB, CSRP3, CTF1, CTNNA3, DES, DMD, DNAJC19, DOLK, DSC2, DSG2, DSP, DTNA, ELAC2, EMD, EYA4, FHL1, FHL2, FKRP, FKTN, FLNC, FXN, GAA, GATA4, GATA6, GATAD1, GLA, GPD1L, HCN4, HRAS, ILK, JPH2, JUP, KCNE1, KCNE2, KCNE3, KCNH2, KCNJ2, KCNJ5, KCNJ8, KCNQ1, KRAS, LAMA4, LAMP2, LDB3, LMNA, MAP2K1, MAP2K2, MIB1, MTO1, MYBPC3, MYH6, MYH7, MYL2, MYL3, MYLK2, MYOM1, MYOZ2, MYPN, NDUFB11, NEBL, NEXN, NF1, NKX2-5, NPPA, NRAS, PDLIM3, PKP2, PLN, PRDM16, PRKAG2, PTPN11, RAF1, RANGRF, RASA1, RBM20, RIT1, RRAS, RYR2, SCN1B, SCN3B, SCN4B, SCN5A, SDHA, SGCD, SHOC2, SLC22A5, SNTA1, SOS1, SOS2, SPRED1, TAZ, TBX20, TCAP, TGFB3, TMEM43, TMEM70, TMPO, TNNC1, TNNI3, TNNT2, TPM1, TRDN, TTN, TTR, TXNRD2, VCL, YWHAE.

ICD-10 DIAGNOSIS CODES: ---------- ---------- ---------- ---------- ---------- ---------- ---------- ---------- ----------

## PATIENT CONSENT

**By signing below you confirm that the ordering healthcare provider: (a) has an on-going relationship with the patient, (b) will use the results in the management of the patient's medical condition, (c) will follow up with the patient once the test results are received to render additional treatment decisions based on the test results, (d) will maintain a detailed chart with extensive SOAP notes specifying how the test results impacted the medical care and treatment of the patient in follow-up visits, (e) understands that if the patient is a Medicare beneficiary that Medicare does *not* cover routine screening tests, and (f) certifies under the penalties of perjury that the test ordered is *not* a screening test, and that all local and national CMS coverage guidelines to determine medical necessity of the ordered test have been met.**

## MEDICAL NECESSITY FOR TESTING

This test is medically necessary for the diagnosis or detection of a disease, illness, impairment, syndrome or disorder and these results will be used in the medical management and treatment and treatment for this patient.
Furthermore, recipients' information is true and correct to the best of my knowledge.
The person listed as ordering Physician or genetic counselor is authorized by law to order the test(s) requested herein. I Confirm that I have provided genetic testing information to the patient and they have consented to genetic testing.

**■ Please check all that apply:**

☐ I confirm that the above patient's gene testing is medically necessary and the result will be used to assess patient for future cardiac conditions risk.
☐ I agree to allow ACCURATE DX LLC, to transfer the information contained in this requisition to an LMN (Letter of Medical Necessity) using the ordering physician's name as his/her signature for the insurance billing purposes.
☐ I have attached a LMN for insurance billing purposes.
☐ Patient meets clinical/genetic testing criteria for the above ordered tests.

Signature if other than Patient's

Printed Name: ----------

PATIENT'S OF RESPONSIBLE PARTY'S SIGNATURE

DATE: ----------

PROVIDER'S SIGNATRE ---------- DATE ----------

## TEST SUBMISSION CHECKLIST

☐ Copy of Patient Demographics
☐ Current Meds List
☐ ICD-10 Diagnosis Codes.
☐ Patient's/Provider's Signatures.
☐ Copy of Insurance Card (Front/Back)
☐ Cardiac Clinical, Personal/Family History Questionnaire.
☐ Attach Patient's Insurance Pre-Authorization Form.

Collected by ----------
Print Name ----------
Signature ----------

## HEREDITARY CARDIAC GENETIC TESTING LETTER OF MEDICAL NECESSITY

# COMPREHENSIVE CARDIOMYOPATHY NGS PANEL.

(210) 571 - 1300
422 W Nakoma Dr
San Antonio, TX 78216

Date of Service : ----------

Patient Name : ----------

Patient Date of Birth : ----------

ICD-10 Diagnosis Code : ----------

## Clinical Evidence and Guidelines for Testing

The Cardiomyopathy Panel includes germline analysis of genes involved in conditions that include severe cardiovascular manifestations, including sudden cardiac arrest and sudden cardiac death. Panel testing includes both sequencing and deletion/duplication analysis of multiple genes simultaneously.

Cardiomyopathy is defined as disease of the heart muscle and has many different presentations, including hypertrophic cardiomyopathy (HCM), dilated cardiomyopathy (DCM), left ventricular noncompaction (LVNC), and arrhythmogenic right ventricular dysplasia/cardiomyopathy (ARVC). It also occurs in Noonan syndrome and other RASopathies, which can also include hematologic disorders and increased cancer risk. There is a broad range of clinical severity, from asymptomatic disease to progressive deterioration of cardiac function and even sudden cardiac death.

Diagnosis of cardiomyopathy can most often be established with noninvasive cardiac imaging, including echocardiography and/or cardiac magnetic resonance imaging (cardiac MRI). However, when imaging results are absent, subtle, or non-specific, molecular diagnosis with genetic testing aids in diagnosis, management and establishing recurrence risk for family members. Hereditary cardiomyopathy can be inherited in an autosomal dominant, autosomal recessive, X-linked, or mitochondrial manner.

Multiple national and international medical societies have published guidelines that recommend genetic testing for cardiomyopathies:

- In 2018, the Heart Failure Society of America (HFSA) published a guideline in conjunction with the American College of Medical Genetics and Genomics (ACMG) that recommends genetic testing for cardiomyopathies using multi-gene testing panels. The recommendation cites studies demonstrating the cost-effectiveness of genetic testing, the importance of results in determining specific interventions that can improve survival and reduce morbidity, and the benefits of cascade screening for family members.[3]
- The 2011 American College of Cardiology Foundation / American Heart Association (ACCF/AHA) guideline for the diagnosis and treatment of hypertrophic cardiomyopathy recommends genetic testing for HCM and other genetic causes of unexplained cardiac hypertrophy in patients with an atypical clinical presentation of HCM or when another genetic condition is suspected to be the cause.[6]
- The Task Force for the Diagnosis and Management of Hypertrophic Cardiomyopathy of the European Society of Cardiology (ESC) recommends genetic testing in patients fulfilling diagnostic criteria for HCM, including to enable genetic testing of at-risk relatives, by a certified diagnostic laboratory with expertise in the interpretation of cardiomyopathy-related variants.[7]
- The Heart Rhythm Society / European Heart Rhythm Association (HRS/EHRA) Expert Consensus Statement on the State of Genetic Testing for the Channelopathies and Cardiomyopathies states that comprehensive or targeted HCM and DCM genetic testing is recommended, and comprehensive or targeted genetic testing can be useful for patients satisfying task force diagnostic criteria LVNC.[8]

## Patient Clinical Utility and Medical Management Implications

The results of this testing will guide appropriate medical management for this patient, including surveillance, preventive measures, and medical and surgical treatment. Treatment for cardiomyopathy and surveillance for progression is critical and is strongly influenced by knowledge of the underlying genetic cause.[1-5] Cardiomyopathies are medically actionable disorders with well-established treatments and interventions that can reduce morbidity and improve survival.[1-5] Furthermore, cardiomyopathy may have a syndromic cause, such as in Danon disease, Fabry disease, mitochondrial myopathy, or muscular dystrophy.[1,3] These disorders, which may be subtle or difficult to diagnose without genetic testing, require further condition-specific medical management, screening, and diagnosis, which is imperative for appropriate treatment.

Management for cardiomyopathies is summarized in specific consensus documents from the American College of Cardiology Foundation / American Heart Association (ACCF/AHA), the European Society of Cardiology (ESC), the Heart Failure Society of America (HFSA).[6,7,9-12]

**Provider Name:** ----------

**Ordering Clinician Signature:** ---------- **Date:** ----------

VR23240819

# Physician Authorization Form

**Name** _____ **Date:** ____/_____/_____

I authorize E.H.E., Inc. to process test ordering documentation on my behalf. My signature also serves as verification that I will ensure any and all laboratory tests are ordered under my authorization and are medically necessary to ensure patient compliance with the therapy I have prescribed. I understand that E.H.E., Inc. may use any of its laboratory relations or reference partners to perform the ordered tests. I agree to notify E.H.E., Inc. when I choose to no longer serve as an ordering physician within a processing relationship with E.H.E., Inc.

**Signature Record**

| Provider Name | Signature | NPI # (REQUIRED) |
|---|---|---|
| _____ (Please Print) | _____ | ☐☐ ☐☐ ☐☐ ☐☐☐☐ ○ MD ○ DO ○ PA ○ ARNP ○ Other |
| _____ (Please Print) | _____ | ☐☐ ☐☐ ☐☐ ☐☐☐☐ ○ MD ○ DO ○ PA ○ ARNP ○ Other |
| _____ (Please Print) | _____ | ☐☐ ☐☐ ☐☐ ☐☐☐☐ ○ MD ○ DO ○ PA ○ ARNP ○ Other |
| _____ (Please Print) | _____ | ☐☐ ☐☐ ☐☐ ☐☐☐☐ ○ MD ○ DO ○ PA ○ ARNP ○ Other |

Note: I understand and hereby acknowledge that I will only order tests that I believe to be medically necessary to ensure patient compliance with the therapy that I have prescribed. I acknowledge that if required by Medicare, Medicaid, or any payers that I will supply E.H.E., Inc. with supporting medical records justifying medical necessity so that they may be relayed to the testing laboratory. The Office of Inspector General (OIG) also takes the position that a provider who orders medically unnecessary tests for which Medicare reimbursement is claimed, may be subject to civil penalties.