

 $\ \ \, \square \,\, \text{Diagnostic} \,\, \square \,\, \text{Family history} \,\, \square \,\, \text{Positive or normal control} \,\,\, \square \,\, \text{Other....}$ Will Patient management be changed depending on the test results? $\ \square$ Yes $\ \square$ No

Address: 3600 South Gessner Rd STE 110 Houston, TX 77063 CLIA – 45D1061571 Lab Director - Albert Chen M.D. Phone: 281-378-2116 Fax: 281-466-2483

LEASE SUBMIT 1	THE FOLLOWING WITH	REQUISITION FORM
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☐ Letter of Medical Necessity (Signed by Physician)
☐ Informed Consent Form (Signed by Pt & Physician)
☐ SOAP & Progress Note (Signed by Physician)
☐ Summary of Active Medications
☐ Scanned Insurance Card Copy

	CARDIOVASCU	LART	EST REQUISIT	ION FOR	M		
	PATI	ENT II	NFORMATION				
Patient First Name			nt Last Name	Biological Sex F M			
Date of Birth (MM/DD/YYYY) Phone Numb		per			Email	Email Address	
Address		City			State	Zip	
Ethnicity: African American	Asian 🗌 Caucasian	Hisp	panic	shkenazi) 🗌	Portuguese	Other	
PATIENT INSU	RANCE INFORMATION			SPECII	MEN INFO	RMATION	
☐ Insurance ☐ Self-Pay ☐ Client Bill			Date Sample Collected (mm/dd/yy) (required)				
Name of the insurance	Secondary Insurance, If	any	Medical Record#				
Insurance Policy/ID number	Name of the insured		☐ Buccal Swab ☐ Other (specify source)				
Insurance Group number	Date of Birth of Insured						
ORDERII	NG PHYSICIAN/SENDIN	NG FAC	CILITY (Each Listed	l person will r	eceive a copy of	f the report)	
Facility Name (Facility Code):		Addre	ess:		City:		
State/Country:		Zip:			Phone:		
Ordering Licensed Provider Name (Last, First)(Code)		NPI# PI		Phone		Fax/Email	
Additional Results Recipients	,						
Genetic Counselor or Other Medica	al Provider Name (Last, First)(Coo	de)		Phone/F	ax/Email		
Signature Required for Proce	ssing Medical Professional	Signatu	ire:			Date:	
	STATEMEN	T OF N	IEDICAL NECE	SSITY			
By submission of this test requisition as the ordering provider is authoring the requisition form are reasonable a disorder; (iv) the test results will de (v) have obtained this patient's and appropriate diagnosis code(s) are in	zed by law to order the test(s) re nd medically necessary for the termine my patient's medical m I relatives', when applicable, writ	equested diagnos anageme ten infor	; (iii) certify that any is and/or treatmen ent and treatment c med consent to und	y custom par t of a diseas lecisions of t	nel and/or ord se, illness, imp his patient's co	lered test(s) requested on this test pairment, symptom, syndrome or ondition on this date of service;	
Signature of Provider (required)						Date:	
INDICATIONS FOR TEST	TING (CHECK ALL THAT APPLY)					

CLINICA	L HISTORY (PLEASE SU	JPPLY CLINIC NOTES A	ND PEDIGREE)		
☐ No personal history of cardiovascular disease		Types (s) of Arrhythm	ia:		
Sudden Cardiac arrest ☐ Y ☐ N (if yes): # Episodes:Age first incident:		☐ Clinical diagnosis of Marfan Syndrome or other connective tissue disorder			
Syncope YN (if yes): Episodes:Age first incident:		Aortic Aneurysm/Dilation Age at dz:z-score:z-score			
History of Cardiovascular ☐ Y ☐ N Age at dx:		☐ Other Aneurysm Loca	ation:Age at dz:Age		
		☐ Aortic/Vascular Disse	ction Location:Age at dz:		
Type(s) of Cardiovascular:		☐ History of Familial hy	percholesterolemia		
History of Arrhythmia 🔲 Y 🔲 N Age at dx:		Other history:			
CLINICAL I	INFORMATION (DETAILE	O MEDICAL RECORD	S MUST BE ATTACHED)		
Is this person affected: ○ Yes ○ No Clinical diagnosis:	•				
Reason for testing: \bigcirc Diagnosis \bigcirc Presymptomatic diagn	osis Carrier/Familial Variant Te	sting			
Please check all that apply. This is not a substitute for submit	ting clinical records.				
Diagnosis	Marfan/TAAD/HDCT		Abnormal heart morphology		
O Amyloidosis	 Aortic/Arterial aneurysm 		Bicuspid aortic valve		
○ ARVC	O Aortic/Arterial dissection		O Coarctation of aorta		
O Brugada syndrome	 Aortic root dilation 		O Heart murmur		
○ CPVT	 Arachnodactyly 		O Heterotaxy		
○ DCM	 Arterial tortuosity/ectasia 		O Hypoplastic left heart		
O Ehlers-Danlos syndrome	O Arthralgia		O Mitral valve prolapse		
○ HCM	Atypical scarring of skin		O Patent ductus arteriosus		
○ HHT	Beighton score		O Patent foramen ovale		
○ Hypertension	Bifid uvula		O Tetralogy of Fallot		
O Loeys-Dietz syndrome			O Ventricular septal defect		
○ LQT syndrome	O Blue sclerae		O Atrial septal defect		
Noncompaction cardiomyopathy (LVNC)	O Bruising susceptibility		Other:		
O Marfan syndrome	○ Cleft lip		PAH		
O PAH	O Cleft palate		O Pulmonary hypertension		
O RCM	 Craniosynostosis 		Other		
O SQT syndrome	 Cutis laxa 		 Abnormality of the periventricular white matter 		
O Sudden Cardiac Arrest	 Dental crowding 		 Angiokeratomas 		
O Sudden Death	O Dural ectasia		○ Anhydrosis		
	 Ectopia lentis 		O Café-Au-Lait Macules		
Echocardiogram	Flexion contracture		O Hearing impairment:		
O Aortic root dimensions:	O High palate		○ Sensorineural ○ Conductive		
O Z-score:	O Hollow organ rupture:		O Craniosynostosis		
○ EF%:		estinal perforation	O Cystic hygroma		
O LVEDD:		esunai penoration	O Downslanted palpebral fissures		
O Z-score:	Other:		O Dysmorphic features:		
O Max LV wall thickness:	O Hypertelorism		Describe:		
O Normal	O Joint contractures		○ Elevated CPK		
Report Included	 Joint dislocations 		O Hypotonia		
ECG	 Joint hypermobility 		O Increase nuchal translucency		
O Prolonged QTc interval:	 Meets Ghent criteria 		Intellectual disability		
Max QTc:	 Micrognathia / Retrognathia 	(circle what applies)	O Keratoconus		
○ Normal	 Midface retrusion 		O Muscle weakness		
O Report Included	 Mitral valve prolapse 		O Myopathy		
Arrhythmia/Cardiomyopathy	O Myopia		O Renal insufficiency		
O Abnormal atrioventricular conduction	O Osteoarthritis		○ Short neck		
O Atrial fibrillation	O Pectus carinatum		O Thromboembolism		
○ Bradycardia	Pectus excavatum		O Type:		
O Fatty replacement of ventricular myocardial tissue	O Pes Planus				
O Heart transplant	O Pneumothorax				
○ Syncope	Recurrent fractures				
O Torsades de pointe	Retinal detachment				
O Ventricular tachycardia	O Scoliosis/Kyphosis (circle w	hat applies)	Attach pedigree and/or include additional clinical information:		
ннт	O Skin findings, Specify:				
O Arteriovenous malformation	○ Stroke	_			
O Epistaxis	Tall stature				
O Telangiectasia	O Velvety skin				
Dislipidemias	•				
Atherosclerosis					
O Corneal Arcus					
O LDL-C levels					
O Xanthomatosis					
Other:					
O ULIGI.	·				

Targeted Single Gene Testing Panel (Select	the genes below) or	Comprehensive	Cardiovascul	ılar NGS Testing Panel (Test All Genes)		
□ ACADVL □ CBL □ ACTA1 □ COL1A1 □ ACTC1 □ COX15 □ ACTN2 □ CRYAB □ AGK □ CSRP3 □ AGL □ DES □ APOA1 □ DMD	DSG2 DSP EFEMP2 ELAC2 ELN EMD EPG5 EYA4	FXN GAA	□ LMNA □ MYBPC3 □ MYH7 □ MYL2 □ MYL3 □ NDUFAF2 □ PKP2 □ PLN □ PRKAG2 □ RAF1	□ SCN5A □ TNNC1 □ SCNN1A □ TNNI3 □ SCNN1B □ TNNT2 □ SGCD □ TPM1 □ SLC22A5 □ TTN □ SLC25A4 □ TTR	3	
ICD-10 DIAGNOSIS CODES WITH DESCRIPTION						
 □ E78.49 - Other Hyperlipidemia □ E78.5 - Hyperlipidemia, unspecified □ E87.1 - Hypo - osmolality and / or hypernatremia □ G89.29 - Other Chronic Pain □ I10 - Essential (Primary) Hypertension □ I25.10 - Atherosclerotic heart disease of native coronary artery without angina pectoris □ I25.5 - Ischemic Cardiovascular □ I25.6 - Silent Myocardial Ischemia □ I25.89 - Other forms of chronic ischemic heart disease □ I25.9 - Chronic ischemic heart disease, unspecified □ I34.1 - Nonrheumatic mitral (valve) insufficiency □ I34.2 - Nonrheumatic mitral (valve) stenosis □ I35.8 - Other nonreheumatic mitral valve disorders □ I34.9 - Nonrheumatic mitral valve disorder, unspecified □ I35.0 - Nonrheumatic aortic (Valve) stenosis □ I35.1 - Nonrheumatic aortic (Valve) Insufficiency 	□ 135.2 - Nonrheumatic ac □ 135.8 - Other Nonrheum □ 135.9 - Nonrheumatic ac □ 142.0 - dilated Cardiova □ 142.5 - Other restrictive □ 142.9 - Supraventricula □ 149.2 - Junctional prem □ 148.0 - Paroxysmal atria □ 149.91 - Unspecified atr □ 149.8 - Other specified □ R00.1 - Bradycardia, un □ 150.9 - Heart Failure, ur □ 150.21 - Acute systolic (□ 150.32 - Chronic diastol □ 150.33 - Acute on chron □ 151.9 - Heart disease, u □ 152 - Other heart dise □ R55 - Syncope and Cc □ R60.0 - Localized edem	natic aortic (valve) disc aortic valve disorder, u ascular e Cardiovascular r tachycardia nature depolarization al fibrillation orillation rial fibrillation cardiac arrhythmias aspecified congestive) heart failur c(congestive) heart failur	orders inspecified re ure ilure e) heart failure	 □ R60.1 - Generalized edema □ R60.9 - Edema, unspecified □ R00.2 - Palpitations □ R06.02 - Shortness of breath □ R06.00 - Dyspnea, unspecified □ R06.09 - Other forms of dyspnea □ PR06.3 - Periodic breathing □ R06.89 - Other abnormalities of breathing □ R07.9 - Chest pain, unspecified □ R07.2 - Precordial pain □ R07.82 - Intercostal pain □ R07.89 - Other chest pain □ R07.89 - Other chest pain □ R94.31 - Nonspecific abnormal electrocardiogram (ECG)(EKG) □ Z79.01 - Long term (current) use of anticoagul □ Z01.810 - Encounter for preprocedural cardiovascular examination □ Z01.812 - Encounter for preprocedural laboratory examination □ Z01.818 - Encounter for other 	lants	
Additional ICD10 codes:						
INFORMED CONSENT						

For the purposes of this consent, "I", "my", and "your" will refer to me or to my child, including my unborn child, if my child is the person for whom the healthcare provider has ordered testing.

PURPOSE OF THIS TEST

The purpose of this test is (a) to see if I may have a genetic variant or chromosome rearrangement causing a genetic disorder; or (b) to evaluate the chance that I will develop or passon a genetic disorder in the future. If I already know the specific gene variant(s) or chromosome rearrangement that causes the genetic disorder in my family, I agree to inform the laboratory of this information.

WHAT TYPE OF TEST RESULTS CAN I EXPECT FROM GENETIC TESTING?

- 1. Positive: A change in your DNA was found, which is very likely the cause of your features/symptoms. This is the most straightforward test result, which can be used as the basis to test other family members to determine their chances of having either the disease or a child with the disease.
- 2. Negative: No variants were found to explain your symptoms. This does not mean that you do not have a genetic condition. It is still possible that there is a genetic variant not found by the test that was ordered. Your healthcare provider or genetic counselor may discuss more testing either now or in the future.
- 3. Variant of Uncertain Significance (VUS): A change in a gene was found. However, we are not sure whether this variant is the cause of your symptoms/features. More information is needed. We may suggest testing other family members to help figure out the meaning of the test result.
- 4. Unexpected Results: In rare instances, this test may reveal an important genetic change that is not directly related to the reason for ordering this test. For example, this test may find you are at risk for another genetic condition I am not aware of or it may indicate differences in the number or rearrangement of sex chromosomes. We may disclose this information to the ordering healthcare provider if it likely affects medical care. Because medical and scientific knowledge is constantly changing, new information that becomes available may supplement the information **Elite Clinical Laboratory** used to interpret my results.

Healthcare providers can contact **Elite Clinical Laboratory** at any time to discuss the classification of an identified variant.

WHAT IS TRIO/DUO-BASED GENETIC TESTING?

For some genetic tests, including samples from the biological parents and/or other biological relatives along with the patient's sample can help with the interpretation of the test results. These tests are often referred to as "trio tests" since they typically include samples from the patient and both parents. Samples from relatives should be submitted with the patient's sample. Clinical information must be provided for the patient and any relative who submits a sample.

I understand that **Elite Clinical Laboratory** will use the relative sample(s) when needed for the interpretation of my test results and that my test report may include clinical and genetic information about are relative when it is relevant to the interpretation of the test results. I further understand that relatives will not receive an independent analysis of data nor a separate report.

RISKS AND LIMITATIONS OF GENETIC TESTING

- 1. In some cases, testing may not identify a genetic variant even though one exists. This may be due to limitations in current medical knowledge or testing technology.
- 2. Accurate interpretation of test results may require knowing the true biological relationships in a family. I understand that if I fail to accurately state the biological relationships in my family, it could lead to incorrect interpretation of the test results, incorrect diagnoses, and/or inconclusive test results. If genetic testing reveals that the true biological relationships in a family are not as I reported them, including non-paternity (the reported father is not the biological father) and consanguinity (the parents are related by blood), I agree to have these findings reported to the healthcare provider who ordered the test.
- 3. Although genetic testing is highly accurate, inaccurate results may occur. These reasons include, but are not limited to mislabeled samples, inaccurate reporting of clinical/medical information, rare technical errors, or other reasons.
- 4. I understand that this test may not detect all of the long-term medical risks that I might experience. The result of this test does not guarantee my health and that additional diagnostic tests may still need to be done.
- 5. I agree to provide an additional sample if the initial sample is not adequate.

PATIENT CONFIDENTIALITY AND GENETIC COUNSELING

It is recommended that I receive genetic counseling before and after having this genetic test. I can find a genetic counselor in my area at www.nsgc.org. Further testing or additional consultations with a healthcare provider may be necessary.

To maintain confidentiality, test results will only be released to the referring healthcare provider, the ordering laboratory, to me, to other healthcare providers involved in my care, diagnosis and treatment, or to others with my consent or as permitted or required by law. Federal laws prohibit unauthorized disclosure of this information. More information can be found at: www.genome.gov/10002077

INTERNATIONAL SAMPLES

If I reside outside the United States, I attest that by providing a sample for testing, I am not knowingly violating any export ban or other legal restriction in the country of my residence.

SAMPLE RETENTION

After testing is complete, my sample may be de-identified and be used for test development and improvement, internal validation, quality assurance, and training purposes. **Elite Clinical Laboratory** will not return DNA samples to you or to referring healthcare providers, unless specific prior arrangements have been made. I understand that samples from residents of New York State will not be included in the de-identified research studies described in this authorization and will not retain them for more than 60 days after test completion, unless specifically authorized by my selection. The authorization is optional, and testing will be unaffected if I do not check the box for the New York authorization language. **Elite Clinical Laboratory** will not perform any tests on the biological sample other than those specifically authorized.

DATABASE PARTICIPATION

De-identified health history and genetic information can help healthcare providers and scientists understand how genes affect human health. Sharing this de-identified information helps healthcare providers to provide better care for their patients and researchers to make new discoveries. Elite Clinical Laboratory shares this type of information with healthcare providers, scientists, and healthcare databases. Elite Clinical Laboratory will not share any personally identifying information and will replace the identifying information with a unique code not derived from any personally identifying information. Even with a unique code, there is a risk that I could be identified based on the genetic and health information that is shared. Elite Clinical Laboratory believes that this is unlikely, though the risk is greater if I have already shared my genetic or health information with public resources, such as genealogy websites.

INFORMED CONSENT

EXOME/GENOME SEQUENCING SECONDARY FINDINGS

Applicable Only for Full Exome Sequencing and Genome Sequencing Tests. • Does not pertain to Xpanded® or Slice tests

As many different genes and conditions are analyzed in an exome or genome sequencing test, these tests may reveal some findings not directly related to the reason for ordering the test. Such findings are called "incidental" or "secondary" and can provide information that was not anticipated.

Secondary findings are variants, identified by an exome or genome sequencing test, in genes that are unrelated to the individual's reported clinical features.

The American College of Medical Genetics and Genomics (ACMG) has recommended that secondary findings identified in a specific subset of medically actionable genes associated with various inherited disorders be reported for all probands undergoing exome or genome sequencing. Please refer to the latest version of the ACMG recommendations for reporting of secondary findings in clinical exome and genome sequencing for complete details of the genes and associated genetic disorders. Reportable secondary findings will be confirmed by an alternate test method when needed.

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WHAT WILL BE REPORTED FOR THE PATIENT? - All pathogenic and likely pathogenic variants associated with specific genotypes identified in the genes (for which a minimum of 10X coverage was achieved by exome sequencing or a minimum of 15X coverage was achieved by genome sequencing), as recommended by the ACMG.

WHAT WILL BE REPORTED FOR RELATIVES? - The presence or absence of any secondary finding(s) reported for the proband will be provided for all relatives analyzed by an exome or genome sequencing test.

LIMITATIONS - Pathogenic and/or likely pathogenic variants may be present in a portion of the gene not covered by this test and therefore are not reported. The absence of reportable secondary findings for any particular gene does not mean there are no pathogenic and/or likely pathogenic variants in that gene. Pathogenic variants and/or likely pathogenic variants that may be present in a relative, but are not present in the proband, will not be identified, or reported. Only changes at the sequence level will be reported in the secondary findings report. Larger deletions/duplications, abnormal methylation, triplet repeat or other expansion variants, or other variants not routinely identified by clinical exome and genome sequencing will not be reported.

FINANCIAL AGREEMENT AND GUARANTEE - For insurance billing, I understand and authorize **Elite Clinical Laboratory** to bill my health insurance plan on my behalf, to release any information required for billing, and to be my designated representative for purposes of appealing any denial of benefits. I irrevocably assign to and direct that payment be made directly to I understand that my out-of-pocket costs may be different than the estimated amount indicated to me by **Elite Clinical Laboratory** as part of a benefit investigation. I agree to be financially responsible for any and all amounts as indicated on the explanation of benefits issued by my health insurance plan. If my insurance provider sends a payment directly to me for services performed by **Elite Clinical Laboratory** on my behalf, I agree to endorse the insurance check and forward it to **Elite Clinical Laboratory** within 30 days of receipt as payment towards **Elite Clinical Laboratory** claim for services rendered.

MEDICARE

A completed Advance Beneficiary Notice (ABN) is required for Medicare patients.

DIGITAL PATIENT LETTER CONSENT

- Applicable Only for Commercial Insurance
- Estimate is provided by your health insurance company and therefore NO estimate will be sent for any orders placed with federal or state-funded insurance plans (e.g. Medicare, Medicaid, Tricare, etc.), institutional bill, or patient bill (self-pay).

To provide you with the estimated out-of-pocket expenses related to your test, **Elite Clinical Laboratory** will send you an email and/or text with the link to access your personalized Digital Patient Letter.

In order to send this information, we need your consent and agreement to the following items:

- 1. can use your email address or mobile phone number solely for the purpose of **Elite Clinical Laboratory** sending your estimated financial obligation. Text message data rates may apply. is not responsible for undelivered messages due to incorrect or illegible contact information.
- 2. will send you an email and/or text message containing a link to view your personalized Patient Letter that includes the test out-of-pocket estimate. The link is time-sensitive and will only be available for 72 hours from the time the message is sent. In order to view the estimate, you must click the link in the message.
- 3. If you take no action, **Elite Clinical Laboratory** will assume that you agree to move ahead with testing and will bill your health insurance. You can approve testing with insurance, switch to self-pay, or cancel the test via the link within the given 72-hour window. In turn, **Elite Clinical Laboratory** if receives your sample(s) and the billing method hasn't been changed, or the test hasn't been cancelled, we will move ahead with testing as ordered, and you will be responsible for any out-of-pocket costs for the completion of the test(s).

STOP Patient Signature

I hereby assign all rights and benefits under my health plan and all rights and obligations that I and my dependents have under my health plan to **Elite Clinical Laboratory** It is assigned affiliates and authorized representatives for laboratory services furnished to me by **Elite Clinical Laboratory** I irrevocably designate, authorize and appoint **Elite Clinical Laboratory** or its assigned affiliates and their authorized representatives as my true and lawful attorney-in-fact for the purpose of submitting my claims, obtain a copy of my health plan document, Summary Plan Description, disclosure, appeal, litigation or other remedies in accordance with the benefits and rights under my health plan and in accordance with federal or state laws. If my health plan fails to abide by my authorization and makes payment directly to me, I agree to endorse the insurance check and forward it to **Elite Clinical Laboratory** immediately upon receipt. I hereby authorize **Elite Clinical Laboratory** its assigned affiliates and authorized representatives to contact me or my health Plan/administrator for billing or payment purposes by phone, text message, or email with the contact information that I have provided to **Elite Clinical Laboratory**, in compliance with federal and state laws. **Elite Clinical Laboratory**, its assigned affiliates and their authorized representatives may release to my health plan administrator, my employer, and my authorized representative my personal health information for the purpose of procuring payment of **Elite Clinical Laboratory** and for all the laboratory services. I understand the acceptance of insurance does not relieve me from any responsibility concerning payment for laboratory services and that I am financially responsible for all charges whether or not they are covered by my insurance.

Signature of Patient or Patient Representative / Relationship to Pation	atient
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Date:

STOP ORDERING PHYSICIAN SIGN HERE Physician must only order tests that are medically necessory for the diagnosis or treatment of a patient

I attest that this test is medically necessary for the diagnosis or detection of a disease or disorder and that the results will be used in medical management and care decisions for the patient. Furthermore, all information on this Requisition Form is true to the best of my knowledge. I agree to provide the Care Plan notes and Letter of Intent for this order if the insurance requests the lab to gather the medical necessity for any reason

Ordering Physician Signature

Date: