Requisition Form

Correlagen Diagnostics, Inc.
www.correlagen.com
Molecular Diagnostics for Genes that Matter™…

Please send sample and completed forms to:
Correlagen Diagnostics, Inc. 307 Waverley Oaks Road, Suite 101, Waltham, MA 02452 Phone: 866-647-0735 Fax: 781-647-0626

Referring Physician/Counselor Information

Institution Name:_____

Name: _____
First MI Last

Medical Specialty:_____NPI#:_____

Genetic Counselor's Name:_____

_____
Address Building/Suite

_____
City/State/Zip

Phone:_____Fax:_____

Email: _____

Report should be: ☐ Faxed ☐ Emailed through Secure Server

Physician/Counselor Statement: I have explained DNA testing to this individual. I have addressed the limitations and benefits of testing and am witness to this patient's choice to have testing. I authorize this test.

_____
Physician/Counselor Signature Date

Cardiology Test Selection (check all that apply)

CARDIO GENE SCAN (Next Generation Sequencing Tests)	
☐ Familial Cardiomyopathy	
☐ Familial Arrhythmia	
☐ Familial Aortopathy	
☐ Noonan and Related Conditions	
☐ Familial Congenital Heart Disease	
☐ Early-Onset Coronary Artery Disease/Familial Hypercholesterolemia	
☐ Family Testing (Please Specify Gene):	
SANGER SEQUENCING TESTS (Below):	
Atrial Septal Defect with Atrioventricular Block	
☐ 190401 NKX2-5	
Arrhythmogenic Right Ventricular Dysplasia/Cardiomyopathy (ARVD/C)	*ARVD/C Individual Genes:* ☐ PKP2 ☐ DSP ☐ DSC2 ☐ DSG2 ☐ TMEM43
☐ 190798 PKP2, DSP, DSC2, DSG2, TMEM43	
Early-onset Coronary Heart Disease	*CHD Individual Genes:* ☐ LDLR ☐ APOB
☐ 190199 LDLR, APOB	
Dilated Cardiomyopathy (DCM)	*DCM Individual Genes* ☐ TNNT2 ☐ TPM1 ☐ MYH7 ☐ ACTC ☐ MYBPC3 ☐ TNNI3 ☐ LMNA
☐ 190598 TNNT2, TPM1, MYH7, MYBPC3, ACTC, LMNA	
Hypertrophic Cardiomyopathy (HCM)	*HCM Individual Genes:* ☐ ACTC ☐ LAMP2 ☐ MYBPC3 ☐ MYH7 ☐ MYL2 ☐ MYL3 ☐ PRKAG2 ☐ TNNT2 ☐ TNNI3 ☐ TPM1
☐ 190398 TNNT2, MYH7, MYBPC3	
☐ 190397 TNNI3, TPM1, MYL2, MYL3, ACTC	
☐ 190396 TNNT2, TNNI3, TPM1, MYBPC3 MYH7, MYL2, MYL3, ACTC	
☐ 190350 TNNT2, MYH7,MYBPC3→ TPM1, TNNI3, MYL2, MYL3, ACTC *(Reflexing occurs if no (probable) disease variant is found)*	
☐ 190395 LAMP2, PRKAG2	
Loeys-Dietz Syndrome	*Loeys-Dietz Syndrome:* ☐ TGFBR1 ☐ TGRBR2
☐ 190698 TGFBR1, TGFBR2	
Marfan Syndrome	
☐ 190601 FBN1	
☐ 190650 FBN1→ TGFBR1, TGFBR2 *(Reflexing occurs if no (probable) disease variant is found)*	
Pulmonic Stenosis	
☐ 190201 PTPN11	
Thoracic Aortic Aneurysms And Dissections	
☐ 190699 FBN1, TGFBR1, TGFBR2	
☐ 190650 FBN1→ TGFBR1, TGFBR2 *(Reflexing occurs if no (probable) disease variant is found)*	

Cancellation requests will only be accepted if received before testing begins.

Sample Specifications

Ship sample overnight at room temperature.

Sample Collection: _____/_____/_____ ☐ A.M. ☐ P.M.
mm dd yyyy

Sample Drawn: ☐ Inpatient ☐ Outpatient

Sample Type (Check One):

☐ Blood Sample (One ≥2 mL whole blood in lavender-top EDTA tube)

☐ DNA (≥ 5 µg at 50 ng/µl in TE preferred)

☐ Other: _____
(Please contact client services before sending other sample types)

Patient Information

Name: _____
First name MI Last Name

Date of Birth: ____/____/_____ Sex: ☐ Male ☐ Female ☐ Unknown
mm dd yyyy

_____
Address Apt #

_____
City/State/Zip

Home Phone:_____Work:_____

Physician Identifier for Patient: _____

Indications for Testing

1. ICD-9 Code (required for billing): _____
2. Test Patient: Historical or current exam findings :

_____

_____

3. Known family history of:

_____

_____

4. Laboratory or other relevant findings:

_____

_____

Ethnic Background:

☐ African American ☐ Ashkenazi Jewish ☐ Asian

☐ Caucasian ☐ Hispanic ☐ Other_____

5. Is this a test for a known familial mutation? ☐ Yes ☐ No

Familial Mutation: _____ _____
Gene (eg, MYH7) Variant (eg, c.746G>A)

If yes, was the family member (index patient) with the known mutation tested at Correlagen?

☐ No, please attach a copy of the original index case report

☐ Yes, please complete the following:

Patient's relation to index patient:_____

Index Patient Name:_____

Index Patient DOB: _____/_____/_____Accession #:_____

Index patient has approved release of information for purposes of this test.

Patient Informed Consent and Financial Acknowledgement

☐ I choose to have testing at this time. ☐ I decline testing at this time.

My signature below indicates that I have read (or had read to me) the information on the **second page** of this form pertaining to Patient Informed Consent and I understand this information.

I understand that I may have a financial responsibility associated with this testing which is related to my insurance coverage and benefit plan and agree that I will make effort to meet this financial obligation.

_____
Signature of Patient/Parent or Legal Guardian Date

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Payment Form

Correlagen Diagnostics, Inc.
www.correlagen.com
Molecular Diagnostics for Genes that Matter™…

Institutional / Client Billing

Institution Name:_____

Department:_____

Billing Contact:_____

_____

Address Building/Suite

_____

City/State/Zip

Phone:_____ Fax:_____

Email:_____

Client Authorization #:_____

Patient Payment Responsibility

Credit card information and signature or payment by check or money order to cover patient co-payment and deductible is required for test processing or if the patient is uninsured.

Credit Card

☐ Master Card ☐ Visa ☐Amex Expiration Date: _____/_____
mm yyyy

Card Number: |__|__|__|__| |__|__|__|__| |__|__|__|__| |__|__|__|__|

Name as it appears on card:_____

_____

Billing Address Apt #

_____

City/State/Zip

Cardholder Signature:_____Date:_____

Credit card payments are processed by Correlagen Diagnostics directly or by MedPro Medical, Correlagen's authorized third party billing agent

Check or Money Order

☐ Enclosed in the amount of $_____

Commercial Insurance Billing

Commercial insurance does not include programs such as Medicare, Medicare HMOs, Medicaid, or Tricare/Champus.

Please include a copy of both sides of the insurance card.

Primary Insurance:_____

Subscriber Name:_____

Subscriber DOB: ____/____/____ Relation to Patient:_____
mm dd yyyy

Member ID#:_____Group Policy #:_____Pre-Auth #:_____

_____

Claims Mailing Address

_____Phone: _____

City/State/Zip

Secondary Insurance:_____

Subscriber Name:_____

Subscriber DOB: ____/____/____Relation to Patient:_____

Member ID#:_____Group Policy #:_____Pre-Auth #:_____

_____

Claims Mailing Address

_____Phone: _____

City/State/Zip

Authorization to Release Information and Pay Benefits

I hereby authorize Correlagen Diagnostics, Inc. (Correlagen) to release all information necessary for reimbursement of my testing to my designated insurance carrier. I authorize that benefits under this claim be paid directly to Correlagen and will remit any insurance payments that I receive to Correlagen. I acknowledge responsibility for 100% of the service price if I fraudulently represent insurance. In the event of underpayment or denial by my insurance carrier, I authorize Correlagen or its designee to bill my secondary insurance carrier (if applicable) and/or attempt to over-turn denial of payment to receive reimbursement for the underpaid claim by the primary insurer.

_____

Patient or Parent/Legal Guardian Signature Date

Patient Informed Consent

By signing this form I understand that:

1. The purpose of this test is to look for genetic changes (called "variants" or "mutations") in one or more genes that are believed to be associated with the condition(s) specified above. Genetic testing may be used to confirm a diagnosis in a person who has an illness or may be used in healthy individuals who have a family history of a genetic condition.
2. By signing this consent, I give my doctor permission to send my blood, DNA, tissue or other type of sample and medical records about me and/or my family history to Correlagen Diagnostics, Inc. I understand that this may help the laboratory to interpret the results of my test.
3. The methods used by Correlagen Diagnostics are highly accurate at detecting specific types of genetic changes. However, all genetic tests have limitations. The testing used does not pick up every kind of change that is associated with disease. In addition, the test may uncover DNA changes that are not well-understood. In some cases, there is not enough information to determine if a change is associated with disease or if it is part of normal variation. In other cases, a change in a gene may be associated with a different condition than the one my doctor ordered the test for.
4. Correlagen has forms with specific statistics on each gene and condition for which it performs DNA testing. These forms can be found on Correlagen's website: www.correlagen.com or my doctor may give me a copy. Correlagen recommends that I read these forms and discuss this test with my doctor or a specialist in genetics, such as a geneticist or genetic counselor.
5. DNA testing performed on multiple family members might uncover non-paternity (e.g. the test indicates that the acknowledged father is not the biological father) or other information about family relationships, such as adoption.
6. Correlagen will release the results of this test only to the ordering physician or to persons designated by me or my physician with my written permission, unless otherwise required by law.
7. Correlagen may contact my physician if new information affects the interpretation of previously reported test results. Correlagen will not contact another physician or individual without my written permission.
8. I understand that Correlagen will retain and store my sample(s) in the event that additional testing is desired by myself or my doctor. Original blood and buccal samples are stored at 4º C until extraction is complete. After extraction is complete, all original blood samples and extracted DNA are stored at -20º C for a minimum of 2 years. They may be discarded after 2 years if all testing is complete and reported.

   □ I do not want the laboratory to retain my sample for more than 60 days or after the testing ordered here has been completed.

   A. If additional testing is desired by myself or my doctor, my doctor is responsible for obtaining my informed consent and for sending a written request to Correlagen.

   B. Correlagen may store my sample after the test is complete to use for research purposes. Prior to any research study, Correlagen will remove my name and any other identifying information from my sample and my clinical information. I understand that this may contribute to new inventions and that I will not receive any financial benefits from such developments.

   □ I do not want my sample and clinical information to be used for research purposes.
9. My signature above indicates that I have read and understand this information and my questions have been answered. In cases when the patient is a minor or is otherwise unable to give consent, a parent, legal guardian or other legally authorized person should sign on the patient's behalf.

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