Requisition Form

Correlagen®

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

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: ______________________________

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)

Test	Individual Genes
Atrial Septal Defect with Atrioventricular Block	
☐ 190401 NKX2-5	
Arrhythmogenic Right Ventricular Dysplasia/Cardiomyopathy (ARVD/C)	*ARVD/C Individual Genes:*
☐ 190798 PKP2, DSP, DSC2, DSG2, TMEM43	☐ PKP2 ☐ DSP ☐ DSC2 ☐ DSG2 ☐ TMEM43
Early-onset Coronary Heart Disease	*CHD Individual Genes:*
☐ 190199 LDLR, APOB	☐ LDLR ☐ APOB
☐ 252880 LDLR, APOB, PCSK9	☐ PCSK9
Dilated Cardiomyopathy (DCM)	*DCM Individual Genes*
☐ 190598 TNNT2, TPM1, MYH7, MYBPC3, ACTC, LMNA	☐ TNNT2 ☐ TPM1 ☐ MYH7 ☐ ACTC ☐ MYBPC3 ☐ TNNI3 ☐ LMNA
Hypertrophic Cardiomyopathy (HCM)	*HCM Individual Genes:*
☐ 190398 TNNT2, MYH7, MYBPC3	☐ ACTC ☐ LAMP2
☐ 190397 TNNI3, TPM1, MYL2, MYL3, ACTC	☐ MYBPC3 ☐ MYH7
☐ 190396 TNNT2, TNNI3, TPM1, MYBPC3 MYH7, MYL2, MYL3, ACTC	☐ MYL2 ☐ MYL3
☐ 190350 TNNT2, MYH7,MYBPC3→ TPM1, TNNI3, MYL2, MYL3, ACTC *(Reflexing occurs if no (probable) disease variant is found)*	☐ PRKAG2 ☐ TNNT2 ☐ TNNI3 ☐ TPM1
☐ 190395 LAMP2, PRKAG2	
Loeys-Dietz Syndrome	*Loeys-Dietz Syndrome:*
☐ 190698 TGFBR1, TGFBR2	☐ TGFBR1 ☐ TGRBR2
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)*	
Transthyretin Amyloidosis	
☐ 252810 TTR	

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

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)

All samples must have a minimum of **two** identifiers.

Indications for Testing

1. ICD-9 Code (required for billing): ____________________
2. Patient's Historical or current exam findings :
   ____
   ____
   ____
3. Known family history of:
   ____
   ____
   ____
4. Laboratory or other relevant findings:
   ____
   ____
   ____
5. ☐ Check if patient has had a Bone Marrow Transplant (BMT)
6. Ethnic Background:
   ☐ African American ☐ Ashkenazi Jewish ☐ Asian
   ☐ Caucasian ☐ Hispanic ☐ Other____________________
7. 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 **(Required)**

   ☐ 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 an effort to meet this financial obligation.

____
Signature of Patient/Parent or Legal Guardian Date

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

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Correlagen®

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.

Check or Money Order

☐ Enclosed in the amount of $____________________

Commercial Insurance Billing

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

Primary Insurance:____________________
Subscriber Name:____________________
Subscriber DOB: ____/____/____ (mm dd yyyy) Relation to Patient:__________
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 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 and a very rare possibility of error cannot be excluded. 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 extensive information including specific statistics for each gene/condition for which its DNA testing is performed. These documents can be found on Correlagen's website: www.correlagen.com or my doctor may give me copies. Correlagen recommends that I read this information 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 my sample will be securely stored in case re-testing is necessary. Samples are stored according to applicable Federal, State and professional regulations. If no regulation applies, samples will be stored according to lab policy and at the end of that time, the sample will be destroyed.

   ☐ 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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