Correlagen®

International Requisition Form

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

____
Complete Address/Country
____

Home Phone:___________________Work:_____________________

Physician Identifier for Patient: ___________________________

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:_________________________________

____
Complete Address/Country
____

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

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.

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:* ☐ PKP2 ☐ DSP ☐ DSC2 ☐ DSG2 ☐ TMEM43
☐ 190798 PKP2, DSP, DSC2, DSG2, TMEM43	
Early-onset Coronary Heart Disease	*CHD Individual Genes:* ☐ LDLR ☐ APOB ☐ PCSK9
☐ 190199 LDLR, APOB	
☐ 252880 LDLR, APOB, PCSK9	
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)*	
Transthyretin Amyloidosis	
☐ 252810 TTR	

Indications for Testing

1. ICD-9 Code (required for billing): ____________________
2. Patient: 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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Payment and Informed Consent Form

Correlagen Diagnostics, Inc.
www.correlagen.com
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Institutional / Client Billing

Institution Name:____

Department:____

Billing Contact:____

Mailing Address (Including Country):

____

____

____

Phone:________________________ Fax:________________________

Email:____

Client Authorization #:____________________________________

Patient Payment Responsibility

If the patient is responsible for payments, credit card information and signature are required for testing.

Credit Card

☐ Master Card ☐ Visa ☐Amex Expiration Date: ______/______ (mm / yyyy)

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

Name as it appears on card:____________________________________

Billing Address (Including Country):

____

____

____

Cardholder Signature:__________________________ Date:__________

Credit card payments are processed by Correlagen Diagnostics.

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.

Instructions for International Shipment of Specimens

International shipping instructions:

- Enter all required information on the **Customs Letter** included in the International Ordering package. Specify whether shipping blood, DNA, or buccal swab samples.
- Make 3 copies of the completed Customs Letter.
- Place all 3 copies, along with airbill, in the plastic pouch on the package and mark "Attention Customs."
- Do **NOT** seal the pouch so that customs officials can access the documents.

For questions about shipping and handling, please contact Client Services at (781) 647-0604.

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Customs Letter

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

Sender's Name:______________________________

Institution Name:______________________________

Complete Mailing Address:______________________________
(Including Country) ______________________________
____

Phone:______________________ **Date:**______________________

Indicate Type of Human Specimen: ______________________________
(E.g. blood, DNA, buccal swab, or saliva)

Re: International Shipping of Human Specimens

To whom it may concern:

Please be advised that:

The items contained in this shipment under Airbill number____________________ are samples of human
(insert Airbill number)
______________________________ from a patient that will be used for laboratory testing only.
(indicate type of specimen - blood, DNA, buccal swab, or saliva)

The specimens in the shipment are of "Human material containing no animal material or non-human primate material or other non-primate animal material."

We hereby declare that the human specimens contained in this shipment under Airbill number______________________
(Insert Airbill Number)
"are not of tissue culture origin or any imported material that is a human vaccine in final dosage form."

We also state that the human specimens contained in this shipment under Airbill number______________________
(insert Airbill number)
are non-cultured, non-recombinant, non-infectious, containing no animal content and/or bovine serum albumin.

We also declare that the human specimens contained in this package under Airbill number ______________________
(insert Airbill number)
have not had any previous testing.

This shipment is being sent to Correlagen Diagnostics, Inc., a clinical reference laboratory that performs genetic testing services for use by healthcare professionals in clinical practice.

If the above advisories do not meet with customs requirements, please advise. The telephone number is ____________________.
(Sender's telephone #)

Sincerely,

____
(Sender's signature)

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