Correlagen®

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 USA
Phone: 866-647-0735 Fax: 781-647-0626

Patient Information

Name: ____
First name MI Last Name

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

____
Complete Address (Including Country)
____
____

Home Phone:____________________Work:____________________

Physician Identifier for Patient: ____________________

Referring Physician/Counselor Information

Institution Name:____

Name: ____
First MI Last

Medical Specialty:__________________________NPI#:______________

Genetic Counselor's Name:____

____
Complete Address (Including 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

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 **third 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

Sample Specifications

Ship sample overnight at room temperature

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

Sample Drawn: ☐ Inpatient ☐ Outpatient

Sample Type (Check One):

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

☐ DNA ($\geq$ 1 µg at 50 ng/µl in TE preferred)

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

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:
____
____
____
5. Ethnic Background:
☐ African American ☐ Ashkenazi Jewish ☐ Asian
☐ Caucasian ☐ Hispanic ☐ Other____________________
6. 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

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 us at (781) 647-0604.

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Test Selection (check all that apply)

Test	Individual Genes
AUTOSOMAL DOMINANT HYPOCALCEMIA	
☐ 202101 CASR	
BARDET-BIEDL SYNDROME	*Bardet-Biedl Individual Genes:*
☐ 200498 BBS1, BBS2, BBS10	☐ BBS1 ☐ BBS2
☐ 200499 BBS1, BBS2	☐ BBS10
COMBINED PITUITARY HORMONE DEFICIENCY (CPHD)	*CPHD Individual Genes:*
☐ 201699 PROP1, POU1F1	☐ PROP1 ☐ POU1F1
CONGENITAL ADRENAL HYPERPLASIA (CAH)	*CAH Individual Genes:*
☐ 201999 CYP21A2, CYP11B1	☐ CYP21A2 ☐ CYP11B1 ☐ CYP17A1 ☐ HSD3B2 ☐ STAR
CONGENITAL HYPERINSULINISM (CH)	*CH Individual Genes:*
☐ 200299 ABCC8, KCNJ11, GCK, GLUD1	☐ ABCC8 ☐ KCNJ11 ☐ GCK ☐ GLUD1
EARLY-ONSET OBESITY	
☐ 200501 MC4R	
ENDOCRINE HYPERPLASIA	
☐ 200601 HSD11B2	
FAMILIAL HYPERCHOLESTEROLEMIA	*FH Individual Genes:*
☐ 200999 LDLR, APOB	☐ LDLR ☐ APOB
FAMILIAL HYPOCALCIURIC HYPERCALCEMIA	
☐ 200701 CASR	
FAMILIAL MALE-LIMITED PRECOCIOUS PUBERTY	
☐ 200801 LHCGR	
GROWTH HORMONE INSENSITIVITY	
☐ 201303 GHR	
HYPOPHOSPHATEMIC RICKETS	*Hypophosphatemic Rickets Individual Genes:*
☐ 201099 PHEX, FGF23	☐ PHEX ☐ FGF23
IDIOPATHIC GROWTH HORMONE	
☐ 201303 GH1	
☐ 201305 GHRHR	
IDIOPATHIC OSTEOPOROSIS	
☐ 202002 LRP5	
MATURITY ONSET DIABETES OF THE YOUNG (MODY)	*MODY Individual Genes:*
☐ 200199 CEL,HNF4A, GCK, TCF1, IPF1, TCF2	☐ HNF4A ☐ GCK ☐ TCF1 ☐ IPF1 ☐ TCF2 ☐ CEL
MULTIPLE ENDOCRINE NEOPLASIA TYPE 1	
☐ 201801 MEN1	
MULTIPLE ENDOCRINE NEOPLASIA TYPE 2	
☐ 201701 RET	
NEONATAL DIABETES MELLITUS (NDM)	*NDM Individual Genes:*
☐ 201199 IPF1, GCK, KCNJ11	☐ IPF1 ☐ GCK ☐ KCNJ11
NEPHROGENIC DIABETES INSIPIDUS (NDI)	*NDI Individual Genes:*
☐ 201299 AVPR2, AQP2	☐ AVPR2 ☐ AQP2
NOONAN SYNDROME	
☐ 201301 PTPN11	
OSTEOPOROSIS-PSEUDOGLIOMA SYNDROME	
☐ 202001 LRP5	
OSTEOGENESIS IMPERFECTA	*Osteogenesis Imperfecta Individual Genes:*
☐ 201499 COL1A1, COL1A2	☐ COL1A1 ☐ COL1A2
PHEOCHROMOCYTOMA	*Pheochromocytoma Individual Genes:*
☐ 201598 VHL, RET, SDHB	☐ SDHB
PRIMARY ADRENAL INSUFFICIENCY	*Primary Adrenal Insufficiency Individual Genes:*
☐ 201499 AIRE, ABCD1, NR0B1	☐ AIRE ☐ ABCD1 ☐ NR0B1 ☐ CYP21A2 ☐ HSD3B2
SHORT STATURE	
☐ 201302 SHOX	
VON HIPPEL-LINDAU SYNDROME AND PHEOCHROMOCYTOMA	
☐ 201501 VHL	
☐ 201599 VHL, RET	

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

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Payment Form

Correlagen Diagnostics, Inc.
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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: ____/____/____ (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 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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Customs Letter

Correlagen Diagnostics, Inc.
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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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