

ORDERING CLINICIAN/INSTITUTION:

Full Name _____
 NPI _____
 Institution _____
 Address _____
 City _____ State _____ Zip Code _____
 Phone _____ Fax _____
 Email _____
 Report Copy to _____ Title _____
 Phone _____ Fax _____

SPECIMEN INFORMATION

Collection Date: _____ Collection Time: _____ Collected By: _____

INDICATE SPECIMEN TYPE

Specimen must be labeled with at least two patient identifiers
 WHOLE BLOOD in lavender top (EDTA) tube (preferred)
 Minimum volume: Infant 1-2mL Child or Adult 3-7mL
 EXTRACTED DNA (acceptable)
Refer to Specimen requirements at www.pathology.ucla.edu/genomics

SELECT CLINICAL EXOME SEQUENCING OPTION

Individual/Proband only
 Family Trio (Proband and two family members preferred)
 Duo (Proband and 1 family member)
 Quad (Proband and 3 family members)
 If this is a comparator sample:
 1) Proband/Child Full Name: _____ DOB: _____
 2) Indicate: Mother Father Family member, specify: _____
 3) Are all samples submitted on this date? Yes No
 4) Compared to proband, is this individual similarly affected? Yes No
Note: Duo/Trio/Quad testing will begin when all samples and completed paperwork have been received in lab
 Exome re-analysis (attach current clinical note)
 Indicate **UCLA case #** _____

CLINICAL INDICATION(S) REQUIRED, ADDITIONAL DESCRIPTION AS APPROPRIATE

<input type="checkbox"/> Amyotrophic Lateral Sclerosis	<input type="checkbox"/> Cardiomyopathy	<input type="checkbox"/> Epilepsy	<input type="checkbox"/> Primary Immunodeficiency
<input type="checkbox"/> Ataxia	<input type="checkbox"/> Congenital Heart Defect	<input type="checkbox"/> Eye Disorders, unspecified	<input type="checkbox"/> Retinal Disorders
<input type="checkbox"/> Autism	<input type="checkbox"/> Connective Tissue Disorders	<input type="checkbox"/> Kidney Abnormalities	<input type="checkbox"/> Sex Development Disorders
<input type="checkbox"/> Autoimmune Disorders	<input type="checkbox"/> Craniofacial Abnormalities	<input type="checkbox"/> Liver Disease	<input type="checkbox"/> Skeletal Dysplasia
<input type="checkbox"/> Bleeding/Thrombolytic Disorders	<input type="checkbox"/> Deafness	<input type="checkbox"/> Metabolic Disorders	<input type="checkbox"/> Skin Disorders
<input type="checkbox"/> Brain Malformation	<input type="checkbox"/> Developmental Delay	<input type="checkbox"/> Multiple Congenital Anomalies	<input type="checkbox"/> Sudden Infant Death
<input type="checkbox"/> Cancer Susceptibility	<input type="checkbox"/> Diarrheal Disorders	<input type="checkbox"/> Muscular Dystrophy	<input type="checkbox"/> Sudden Unexplained Death
<input type="checkbox"/> Cardiac Arrhythmia	<input type="checkbox"/> Endocrine Disorders	<input type="checkbox"/> Neurologic Disorders, unspecified	<input type="checkbox"/> Vascular Abnormalities
			<input type="checkbox"/> Other: _____

Additional Description: _____
Differential Diagnosis: _____
Additional Suspected Gene(s): _____
 Use approved gene symbols from HGNC (HUGO Gene Nomenclature Committee <http://www.genenames.org>)
Ethnicity: African American Asian Ashkenazi Jewish European Caucasian
 Hispanic Native American Indian Other Jewish
 Other (please specify): _____
Family History:
 Congenital Anomalies Intellectual Disability Multiple Miscarriages
 Parental Consanguinity/degree of relation: _____
 Other: _____
 Please attach clinical note(s) most relevant to the exome sequencing test.
 Test will not start until requisitions, consent and clinical notes are received.

PATIENT NAME (LAST, FIRST, MI) _____
 CLIENT PATIENT ID _____ DATE OF BIRTH _____ GENDER F M
 ADDRESS: _____
 CITY: _____ STATE _____ ZIP CODE _____ PHONE _____

INDICATE PAYMENT OPTION

Bill Insurance Attach demographic sheet with insurance information.
 Authorization number (required) _____
 For assistance with insurance preverification, please contact Client Services at 310-267-2680
 Patient Self Pay (Prepayment Required)
 Credit card or wire transfer, please contact our billing office at 310-267-2680
 Check / money order made payable to UC Regents
 Bill to Referring Institution (U.S. only)

Authorized Billing / Business Office Contact Information:

Printed Name: _____ Signature: _____
 Email: _____ Phone: _____
 Name/Department: _____
 Address: _____
 City: _____ State: _____ Zip Code: _____

Ordering institution accepts financial responsibility for full price of this test.

Outside of the U.S.: Contact our Billing office at 310-267-2680 for payment via credit card or wire transfer.

ICD DIAGNOSIS CODE(S)

Indicate medical necessity for the test requested.

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FOR LAB USE ONLY

Requisition #: _____

DELIVER SAMPLES WITH PAGES 1 & 4 TO UCLA PATHOLOGY OUTREACH SERVICES

10833 LE CONTE AVE, A3-240 CHS, LOS ANGELES, CA 90095-1732 PH 310-267-2680 FX 310-267-2685

KEEP PAGES 2-3 FOR PATIENT, PARENT AND/OR FAMILY MEMBER REFERENCE.

SUBMIT PAGE 5 IF ADDITIONAL FAMILY MEMBER IS INCLUDED IN THIS REQUEST.

MRN:

Patient Name:

CONSENT FOR **POSTNATAL** CLINICAL EXOME SEQUENCING TEST

This document is to provide information about the Clinical Exome Sequencing Test. This information will be discussed with you by a medical geneticist and/or genetic counselor. By signing the Signature Page, you authorize the UCLA Clinical Genomics Center to analyze a sample of your DNA or your child's DNA for the Clinical Exome Sequencing Test.

What is the Benefit of the Clinical Exome Sequencing Test:

The Clinical Exome Sequencing Test is used to identify the genetic cause of a disease or disability in an individual. Genes carry inheritable information, and it is estimated that we have about 20,000 genes in each cell in our body. The combination of all genes in an individual is called the genome. Some important and functional sections of the genome that make protein are called exons. The word 'exome' refers to all exons in the genome. This test analyzes the exons of about 93-97% of all medically relevant genes at the same time and compares it to those of healthy people to identify DNA changes that are related to an individual's medical condition. We do this to try and find the DNA change that has led to your medical condition. The benefit of receiving the information from this test in conjunction with available published medical information at the time of testing is to decide whether these DNA changes are likely to be causing your medical condition.

What are the limitations and risks:

It is important to understand that there may be disease-causing DNA changes (also called incidental findings) that will not be related to your primary clinical concern(s). The symptoms of these other conditions may not be evident at this time, and they may or may not develop in the future. During the course of reviewing your results, we may encounter certain incidental findings which we deem to be medically actionable (where you and/or your physician may want to take action for your future medical benefit). An example of this is variants that are known to be involved in predisposing you to certain types of cancer.

There are also some types of DNA changes that cannot be detected by this test. This test is targeted to analyze the exons; however, there are parts of the exome that are undetectable. In addition, we know that some disease-causing variants do not occur in exons, and this test will not detect those variants either. Your physician may decide that you need other DNA testing in addition to this test. The testing process relies on highly skilled technicians and reliable technology. The methods are reliable, but as with any laboratory test, there is the small chance that an error may occur.

The interpretation of your results will be based on our currently available information. As medical knowledge advances and new discoveries are made, the interpretation of your results may change. It is possible that re-interpretation of your results could lead to new information about your medical condition. Such re-interpretation must be requested by your physician and will involve additional cost. However, it may also not be possible to re-interpret your data at a future date, and it may instead require retesting a new sample from you or your child.

MRN:

Patient Name:

CONSENT FOR **POSTNATAL** CLINICAL EXOME SEQUENCING TEST

In some instances we might need to test other family members to make the result clear. There is a risk that you may learn other genetic information about you or your family members that is not related to any specific medical concern(s). Learning about this information might cause anxiety and psychological stress. As an example, this test may reveal non-paternity and non-maternity (where the father or mother is not the biological parent) or other unexpected familial relationships. Since this type of information may inhibit our ability to fully interpret the results of this test, if this type of information is uncovered by the laboratory during the course of testing, it will be shared with the ordering clinician and documented on the report by the laboratory, and it may also be discussed during the post-test counseling session. Note that there are several alternative testing options where this type of familial information may not be uncovered; these include a proband only exome test (where family members are not tested), a gene panel, or a single gene test.

What is needed:

This test requires 1-2 ml of blood for infants and 3-7 ml (1 teaspoon) of blood for children/adults, which is drawn by needle from a vein.

How long will it take to get the results:

It will take approximately 3 months to obtain results. The results will be sent to your clinician. We recommend both pre- and post-test counseling with a clinical geneticist or genetic counselor.

Reporting of the results:

Clinically significant variants associated with your primary clinical concern(s) will be reported to your clinician. Variants of uncertain clinical significance which are related to your primary clinical concern(s) may also be reported to your clinician (though additional testing of other family members may be recommended to determine the significance of those results).

Consent for Postnatal Clinical Exome Sequencing Test (Parent or Family Member):

I understand that my child or my family member is having the Clinical Exome Sequencing Test performed at the UCLA Clinical Genomics Center. The clinician or the genetic counselor previously discussed the information about this test with me. I have been informed of the potential types of test results and their associated implications. I understand that I am being tested in order to assist with the analysis of my child's or family member's sample and I will not receive a separate report specific to my genetic results. A report will only be generated for my child or family member. If I am found to share the same genetic finding(s) with my child or family member, that information will be included in his/her report.

MRN: _____

Patient Name: _____

CONSENT FOR POSTNATAL CLINICAL EXOME SEQUENCING TEST

Consent for POSTNATAL Clinical Exome Sequencing Test Signature Page

This page must be completed and submitted with the requisition before testing can begin.

Option to report actionable incidental findings:

Should we report any medically actionable incidental findings we may encounter in the patient (which includes the current ACMG secondary findings gene list)? Carrier variants which are not diagnostically relevant to your current clinical indication(s) will not be reported. Please check one:

YES NO

Option for UCLA to use your results:

May we use your results and leftover DNA to improve the Clinical Exome Sequencing Test and to develop additional clinical genetic tests by comparing your data to the data we obtain from other individuals? Please check one:

YES NO

If you wish to be contacted about enrolling in any future research studies that are related to your clinical indication(s), please provide a phone number and/or e-mail address:

Phone) _____ Email) _____

Statement of Understanding:

I have read (or someone has read to me) the information provided in the Consent for Postnatal Clinical Exome Sequencing Test. I have been given an opportunity to ask questions and all of my questions have been answered about this test. By signing this form, I willingly agree to participate in the Clinical Exome Sequencing Test. **(Signatures are required from each individual to be included in the testing.)**

Patient Printed Name: _____

Signature: _____ **Date:** _____ **Time:** _____

If signed by an individual other than the patient (or if the patient is a minor), please indicate your relationship to the patient: Mother Father Other: _____

Printed Name: _____ Relationship: Mother Other: _____

Signature: _____ **Date:** _____ **Time:** _____

Printed Name: _____ Relationship: Father Other: _____

Signature: _____ **Date:** _____ **Time:** _____

Clinician/Genetic Counselor statement: I have explained the Clinical Exome Sequencing Test to this individual. I have addressed the test limitations as outlined on the child's or family member's consent form and have answered this individual's questions about this test.

Clinician's or Genetic Counselor's Name: _____

Signature: _____ **Date:** _____ **Time:** _____

MRN:

Patient Name:

**POST NATAL CLINICAL EXOME SEQUENCING TEST
(PARENT OR FAMILY MEMBER)
CONSENT**

I understand that my child or my family member is having the Clinical Exome Sequencing test performed at the UCLA Clinical Genomics Center. The physician or the genetic counselor previously discussed the information about this test with me. I have been informed of the potential types of test results and their associated implications. I understand that I am being tested in order to assist with the analysis of my child's or family member's sample and I will not receive a separate report specific to my genetic results. A report will only be generated for my child or family member. If I am found to share the same genetic finding(s) with my child or family member that information will be included in his/her report.

By signing this form, I willingly agree to participate in the Clinical Exome Sequencing test.

Printed Name _____

Signature _____ Date _____ Time _____

Relationship to Patient: _____

Physician/Genetic Counselor statement: I have explained the Clinical Exome Sequencing test to this individual. I have addressed the test limitations as outlined on the child's or family member's consent form and have answered this individual's questions.

Physician's or Genetic Counselor's Name _____

Signature _____ Date _____ Time _____

By signing this form, I willingly agree to participate in the Clinical Exome Sequencing test.

Printed Name _____

Signature _____ Date _____ Time _____

Relationship to Patient: _____

Physician/Genetic Counselor statement: I have explained the Clinical Exome Sequencing test to this individual. I have addressed the test limitations as outlined on the child's or family member's consent form and have answered this individual's questions.

Physician's or Genetic Counselor's Name _____

Signature _____ Date _____ Time _____