labcorp | INVITAE

LONG-CHAIN FATTY ACID OXIDATION DISORDERS

ORDER ID
For internal use only

Requisition Form
LC-FAOD TRF987-7

This requisition form can be used to submit an order for the **Long-Chain Fatty Acid Oxidation Disorders Program**, a sponsored testing program for genetic disorders brought to you by **Ultragenyx Pharmaceutical Inc.** and **Labcorp Genetics, Inc**.

INSTRUCTIONS: Review the ordering options and then complete all sections of this form. Your ordering option will be indicated in the test selection section.

ORDERING OPTIONS

1. LONG-CHAIN FATTY ACID OXIDATION DISORDERS PROGRAM

For individuals that meet the eligibility criteria below and wish to receive the program specific genetic testing panels.

REQUIRED: You must select below the appropriate eligibility criteria for this patient.

This program is available to patients in eligible countries who have completed the UltraCare Start Form for LC-FAOD or are suspected of having or have been diagnosed with a long-chain fatty acid oxidation disorder and a plasma acylcarnitine test has been ordered (regardless of result - abnormal or normal.)

Please select at least one of the following and provide a copy of abnormal biochemical confirmatory labs, if available:

- ◯ The patient has completed the UltraCare Start Form for LC-FAOD
- ◯ Carnitine palmitoyltransferase (CPT) IA deficiency is suspected or diagnosed
- ◯ Carnitine-acylcarnitine translocase (CACT) deficiency/Carnitine palmitoyltransferase (CPT) II deficiency is suspected or diagnosed
- ◯ Long-chain 3-hydroxyacyl-CoA dehydrogenase (LCHAD) deficiency/Mitochondrial trifunctional protein (TFP) deficiency is suspected or diagnosed
- ◯ Very long-chain acyl-CoA dehydrogenase (VLCAD) deficiency is suspected or diagnosed

2. GENE-SPECIFIC FAMILY FOLLOW-UP TESTING

For relatives of program participants who received a Pathogenic/Likely Pathogenic result or approved VUS who want to receive gene specific family follow-up testing at no additional charge. Relatives do not need to meet the eligibility criteria listed above. Learn more at **invitae.com/family**.

**Please refer to the program landing page at invitae.com/sponsored-testing for country eligibility*

PATIENT INFORMATION

First name	MI	Last name
Date of birth (MM/DD/YYYY)	Biological sex ◯ M ◯ F	MRN (medical record number)

Ancestry ◯ Asian ◯ Black/African American ◯ White/Caucasian ◯ Ashkenazi Jewish ◯ Hispanic ◯ Native American ◯ Pacific Islander ◯ French Canadian ◯ Sephardic Jewish ◯ Mediterranean ◯ Other: _____

Phone	Email address (report access after clinician releases)	
Address		City
State/Prov	ZIP/Postal code	Country

Ship a kit to this patient (optional) by faxing or emailing this completed form to Labcorp Genetics

Kit type: ◯ Buccal swab kit ◯ Saliva kit

Ship to: ◯ Address above ◯ Alternate address: _____

SPECIMEN INFORMATION

Specimen type: Blood (3-mL purple EDTA) **-OR-** Buccal Swabs (OCD-100, 2 devices) **-OR-** Saliva (Oragene™) **-OR-** DNA source: _____

*We cannot accept blood or oral specimens from patients with active hematologic malignancy, recent leukocyte transfusion, or history of bone marrow/stem cell/liver transplants. DNA must be extracted in a CLIA or other suitably certified lab and cannot be from prenatal or tumor sources. Details at: **invitae.com/specimen-requirements***

Specimen collection date (MM/DD/YYYY): ____ ____ ____

Special cases: ◯ History of/current hematologic malignancy in patient

PARTNER CODE FAOD

CLINICIAN INFORMATION

Organization name		
Phone	Fax	
Address	City	
State/Prov	ZIP/Postal code	Country

Primary clinical contact name (if different from ordering provider)	NPI (US only)
Primary clinical contact email address (for report access)	

Ordering provider (select one ordering provider by marking the checkbox before the name)

	Name	NPI (US only)	Email address (for report access)
◯			
◯			
◯			
◯			
◯			
◯			

Additional clinical or laboratory contacts (optional, to share access to order online)

◯ **Share this order with the primary clinical contact's default clinical team, manage at invitae.com**

Name	Email address (for report access)
Name	Email address (for report access)

CLINICAL HISTORY

FAMILY HISTORY

Is there a family history of disease for which the patient is being tested? ◯ Yes ◯ No If yes, describe below and attach pedigree and/or clinical notes.

Relative's relationship to this patient	Maternal or paternal	Diagnosed condition	Age at diagnosis	Relative's relationship to this patient	Maternal or paternal	Diagnosed condition	Age at diagnosis

PERSONAL HISTORY

Is/was this patient affected or symptomatic?† ◯ Yes ◯ No
Provide details in the required clinical history questions (if applicable).

† Symptomatic means this patient has features or signs known or suspected to be related to the genetic testing being ordered and could include findings on physical examination, laboratory tests, or imaging.

REQUIRED CLINICAL HISTORY

Outcome of Newborn Screen (NBS)

◯ Positive – Suspected disorder: _____
◯ Negative
◯ Unknown

Outcome of confirmatory testing (e.g. acylcarnitine test)

◯ Positive – Disorder: _____
◯ Inconclusive – Disorder(s): _____
◯ Negative

If confirmatory test was positive, what is the reason for conducting this genetic test? (check all that apply)

◯ Payer requirement
◯ Differential diagnosis (between LC-FAOD types)
◯ Distinguish affected versus carrier status
◯ Understand disease course/prognosis
◯ Inform treatment decision
◯ Genetic counseling
◯ Identify at-risk family members
◯ Research
◯ Other: _____

Please provide a copy of the plasma acylcarnitine results. Providing a copy of plasma acylcarnitines results, or any other confirmatory tests, when available, is strongly encouraged. These results are helpful for variant interpretation and in some cases can make a difference for the final interpretation of the variant.

◯ Plasma acylcarnitine or confirmatory results attached
◯ Test results unavailable

What prompted you to suspect this patient may have a long-chain fatty acid oxidation disorder? (Exclude PHI)

Ongoing clinical features: (check all that apply)

◯ Cardiomyopathy
◯ Elevated creatine kinase
◯ Hepatomegaly
◯ Hypoketotic hypoglycemia
◯ Liver failure
◯ Muscle myopathy
◯ Myoglobinuria
◯ Peripheral neuropathy
◯ Reye like syndrome
◯ Rhabdomyolysis
◯ Retinitis pigmentosa
◯ Other: _____

OPTIONAL - REQUESTED VARIANTS FOR THIS PATIENT'S REPORT, IF KNOWN

*To have the presence or absence of specific variants commented on in this patient's report, provide the details below. For gene-specific family follow-up see **Note** under Test Selection.*

The proband's (individual with the variant) gene/variant information is needed for this request. Provide the Invitae Order ID RQ#: _____ **OR** attach a copy of the outside lab results *(required)*

Variant(s) *(e.g. GENE c.2200A>T (p.Thr734Ser) NM_00012345) If left blank, all variants identified in the proband will be commented on.*		**This patient's relationship to proband:**
		◯ Parent ◯ Sibling ◯ Grandchild
		◯ Child ◯ Self ◯ Other: _____

TEST SELECTION – Select test(s) from either option 1 or 2 below:

1. LONG-CHAIN FATTY ACID OXIDATIONS DISORDERS PROGRAM – Indicate test(s) to be performed below:

Test code	Test name	# of genes	Gene list
◯ 06165	Invitae Fatty Acid Oxidation Defects Panel	25	ACAD9, ACADM, ACADS, ACADSB, ACADVL, CPT1A, CPT2, ETFA, ETFB, ETFDH, FLAD1, HADH, HADHA, HADHB, HMGCL, HMGCS2, MLYCD, NADK2, SLC22A5, SLC25A20, SLC25A32, SLC52A1, SLC52A2, SLC52A3, TANGO2

2. GENE-SPECIFIC FAMILY FOLLOW-UP TESTING *For relatives of a program participant ('proband') who received a Pathogenic/Likely Pathogenic result or approved VUS.*

◯ Family follow-up testing for Proband's Invitae Order ID: RQ#_____	**This patient's relationship to proband:** ◯ Parent ◯ Sibling ◯ Grandchild ◯ Child ◯ Other: _____	**Gene(s) to be tested in this patient:**

***NOTE**: The presence or absence of all variants identified in the proband for the gene(s) ordered for gene-specific family follow-up will be commented on in this patient's report unless a limited selection is specified in the **Requested Variants** section above. The laboratory will report any Pathogenic/Likely Pathogenic variants found in this patient for the gene(s) ordered.*

*If an order is placed using an outdated test requisition form, we reserve the right to upgrade ordered tests to their current versions. View current requisition forms online at **invitae.com/forms** or consider placing your order online in the Invitae portal. Note: Test IDs containing add-on codes will include the original panel as well as the add-on.*

Invitae is now part of Labcorp. By signing this form, the medical professional acknowledges that the individual/family member authorized to make decisions for the individual (collectively, the "Patient") has been supplied information regarding and consented to undergo genetic testing, substantially as set forth in Labcorp Genetics' Informed Consent for Genetic Testing (**invitae.com/forms**). Based on this consent, I acknowledge that I permit Labcorp Genetics to de-identify the patient's personal information. The medical professional will retain evidence that the patient consented to genetic testing. The Patient has been informed that Labcorp Genetics may notify them of clinical updates related to genetic test results (in consultation with the ordering medical professional as indicated) and has been informed that deidentified (also referred to as pseudonymized) patient data may be used and shared with third parties in connection with the Program, for research and commercial purposes. For orders originating outside the United States, the Patient has been informed that their personal information and specimen will be transferred to and processed in the United States. The medical professional warrants that (1) he/she will not seek reimbursement for this no-charge test from any third party, including but not limited to government healthcare programs; (2) participation in the Program will not influence his/her medical decisions; (3) he/she is not obligated to purchase or prescribe any product or service offered by a sponsor of the Program; (4) he/she is not obligated to participate in or to encourage patients to participate in any clinical trial or other research program conducted by a sponsor; and (5) he/she will participate in the Program in accordance with applicable laws. The medical professional consents to the sharing of organization and provider contact information with third parties, including commercial organizations, who may contact the medical professional directly in connection with the Program. For California providers only: I have the right to opt-out of certain uses of my data, and additional rights as detailed in Labcorp Genetics' **privacy policy**. If I am a delegate, I confirm I have authorization to (1) agree to all the above and (2) sign this form and any supporting documents for Labcorp Genetics on behalf of the ordering provider. A list of third party partners will be provided upon request. I attest that I am authorized under applicable law to order this test.

Medical professional signature (required)	**Date (MM/DD/YYYY)**

