XLH Confirmatory Testing

SPONSORED GENETIC TESTING TO CONFIRM XLH DIAGNOSIS FOR TREATMENT COVERAGE

What is XLH Confirmatory Testing?

Some insurers require verification of XLH diagnosis before determining patient eligibility for treatment coverage. XLH Confirmatory Testing is a sponsored program that provides genetic confirmation of XLH diagnosis.

Who is eligible for XLH Confirmatory Testing?

Patients are eligible if they are aged **6 months or older** and have a **completed UltraCare® Start Form for XLH**. Testing is available to all eligible patients at no cost.

How do I submit a patient test?

STEP 1
Complete and print both pages of the **Invitae test requisition form**.

STEP 2
Obtain a blood or saliva sample from your patient using the provided Invitae kit.

STEP 3
Mail the form and patient sample using the provided packaging and prepaid label.

It is strongly encouraged to include clinical history information with the form and patient sample, when available. This information is useful for variant interpretation. Test results are usually available within 10 to 21 calendar days. You will be notified via email or fax to access results through Invitae's secure site. Obtain patient permission before sharing test results with the patient's insurance company.

Questions about XLH Confirmatory Testing?

Contact UltraCare at **1-888-756-8657** or online at **ultracaresupport.com**.

Complete the following fillable test requisition form, print it out, and enclose it with the patient sample. The form may also be submitted via fax **415-276-4164** or online at **invitae.com/hypophosphatemia**.

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Sponsored By:
ultragenyx pharmaceutical

INVITAE **HYPOPHOSPHATEMIA**

ORDER ID
For Invitae internal use only

Requisition Form
Hypophosphatemia Sponsored Testing Program TRF942-4

This requisition form can be used to submit a specimen for the Hypophosphatemia* program, a complimentary testing program **for genetic hypophosphatemic disorders** brought to you by Ultragenyx Pharmaceutical, Inc. Patients must meet the eligibility requirements for the program. To submit orders for genetic testing outside of this program, please order through Invitae's online portal or use a standard requisition form, accessible at www.invitae.com/order-forms.

REQUIRED PROGRAM ELIGIBILITY

The patient must be aged 6 months or older and meet one of the following criteria below (select one or more):

- ☐ Has a completed UltraCare® Start Form for XLH
- ☐ Has a previous diagnosis related to hypophosphatemia*
- ☐ Exhibits TWO or more of the following clinical signs and/or symptoms (select two or more):
  - ☐ Family member of a confirmed XLH patient
  - ☐ Muscle pain, weakness, and/or fatigue
  - ☐ Lower limb deformities
  - ☐ Fractures/pseudo-fractures
  - ☐ Tooth abscesses and/or excessive dental caries
  - ☐ Bone, joint pain, and/or joint stiffness
  - ☐ Short stature
  - ☐ Gait abnormalities

*Hypophosphatemic disorders are also referred to as X-Linked Hypophosphatemia, X-linked hypophosphatemic rickets, hereditary hypophosphatemic rickets, familial hypophosphatemic rickets, vitamin D-resistant rickets (VDRR), vitamin D-resistant osteomalacia, X-linked vitamin D-resistant rickets, hypophosphatemic rickets, hypophosphatemic vitamin D-resistant rickets (HPDR), genetic rickets, or familial hypophosphatemia.

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

Address | City

State | ZIP code | Country

SPECIMEN INFORMATION

Label each tube with the patient's full name, date of birth, and specimen collection date.
A requisition form MUST accompany each specimen. www.invitae.com/specimen-requirements

Specimen type : ◯ Blood ◯ Saliva ◯ Assisted saliva

We are unable to accept blood/saliva from patients with:
- *Allogeneic bone marrow transplants*
- *Blood transfusion <2 weeks prior to specimen collection*

Collection date (MM/DD/YYYY)
If not provided, date will be 1 day prior to our receipt of specimen.

Special cases : ◯ History of/current hematologic malignancy

REASON FOR TESTING

Previous results *(if applicable and not included in clinical criteria, enclose copy of report)*

CLINICIAN INFORMATION

Organization name

Phone | Fax

Address | City

State | Zip code | Country

Primary clinical contact

Name | NPI

Email address (for report access)

Ordering provider

◯ **Same as primary clinical contact**

Name | NPI

Email address (for report access)

Additional clinical or laboratory contact (optional)

◯ **Share this order with the primary clinical contact's default clinical team (manage team online at at www.invitae.com/signin)**

Name | Email address (for report access)

INVITAE PARTNER CODE

XLH

Optional clinical history (Please check all that apply.) It is strongly encouraged to include a copy or the values of abnormal results, when available, for this individual or affected family members. This information is useful for variant interpretation.

Biochemical markers: *Patient value/reference range*

- ☐ Reduced serum phosphate (<LLN) _____ /_____
- ☐ Reduced TmP/GFR (<LLN) _____ /_____

FAMILY VARIANT TESTING

Invitae's family variant testing programs involves full analysis of the gene in which the original family member's variant was identified. For more information, visit www.invitae.com/family-testing.

Please attach the proband's clinical report or provide Invitae RQ#

INVITAE PROBAND RQ#	RELATIONSHIP TO PROBAND	GENE(S)	VARIANT(S)

Invitae continually updates its panels based on the most recent evidence. Please note that if an order is placed using an older version of this form, Invitae reserves the right to upgrade any ordered panel(s) to the current version(s).

TESTS INCLUDED IN THE PROGRAM

INVITAE HYPOPHOSPHATEMIA PANEL			
Test code	**Test name**	**# of genes**	**Gene list**
◉ 72039	Invitae Hypophosphatemia Panel	13	ALPL, CLCN5, CYP2R1, CYP27B1, DMP1, ENPP1, FAH, FAM20C, FGF23, FGFR1, PHEX, SLC34A3, VDR

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 Invitae's Informed Consent for Genetic Testing (www.invitae.com/patient-consent)and in connection with the Program, and has been informed that Invitae may notify them of clinical updates related to genetic test results (in consultation with the ordering medical professional as indicated). The medical professional warrants that he/she will retain a written copy of the consent and produce it upon request, and that he/she will not seek reimbursement for this no-cost test from any third party, including but not limited to federal healthcare programs. The medical professional also hereby acknowledges that organization and clinician contact information provided in the order may be shared with third parties, including Ultragenyx, that may contact the medical professional directly in connection with the Program, and that they have made the Patient aware that third parties including Ultragenyx may contact their medical professional regarding de-identified information gathered through the Program. 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 and that de-identified Patient data may be used and shared for research purposes in the United States. In addition to the above, I attest that I am authorized under applicable state law to order this test.

Medical professional signature (required)	**Date**

