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 **1 year or older** and have a **completed CRYSVITA Start Form**. 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 (scroll down).

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.

Test results are usually available within 10 to 21 calendar days. You will be notified via email (or fax, if we do not have your email address) 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**

For your convenience, a fillable test requisition form is included in this PDF. Complete and print the form. Be sure to mail it with the patient blood or saliva sample to ensure timely processing.

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Sponsored By: ultragenyx pharmaceutical

INVITAE **HYPOPHOSPHATEMIA**

ORDER ID
For Invitae internal use only

Requisition Form
XLH Sponsored Testing Program TRF942-1

This requisition form can be used to submit a specimen for the Hypophosphatemia program, a complimentary testing program for the PHEX gene brought to you by Ultragenyx Pharmaceutical. 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.

PROGRAM ELIGIBILITY:

The patient must be aged 1 year or older with a completed CRYSVITA start form.

PATIENT INFORMATION

First name | MI | Last name

Date of birth (MM/DD/YYYY) | 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 ◯ DNA - source:

DNA must be extracted in a CLIA or other suitably certified laboratory

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. For DNA, provide date retrieved from archive.*

Special cases : ◯ History of/current hematologic malignancy ◯ Resubmission

REASON FOR TESTING

Previous results *(if applicable and not included in clinical criteria)*

ORGANIZATION INFORMATION

Organization name and address

Organization name

Phone | Fax

Address | City

State | Postcode | Country **United States**

Primary clinical contact

Name

Role/title | Phone

Email address (for report access)

Ordering physician

◯ **Same as primary clinical contact**

Name

Email address (for report access)

Additional clinical or laboratory contact (optional)

Name | Email address (for report access)

INVITAE PARTNER CODE XLH

Biochemical markers (optional):

	Patient value/reference range
☐ Reduced serum phosphate (<LLN)	_____ /_____
☐ Reduced TmP/GFR (<LLN)	_____ /_____

ASSAY

Invitae is a CAP-accredited and CLIA-certified clinical diagnostic laboratory performing full-gene sequencing and deletion/duplication analysis using next-generation sequencing technology (NGS). Search for details on the analysis of any gene in our test catalog at **www.invitae.com/physician/search**.

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 PHEX TEST			
Test code	**Test name**	**# of genes**	**Gene list**
◉ 72038	Invitae PHEX Test	1	PHEX

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 the ordering physician, or I am authorized by the ordering physician to order this test, or I am authorized under applicable state law to order this test.

Medical professional signature	**Date**

