SPECIAL PROJECT - TEST REQUISITION FORM

SP318 - Alnylam Act® Primary Hyperoxaluria Type 1

SPONSORED TESTING PROGRAM

Skip the paperwork - ORDER THIS TEST ONLINE!

- Avoid paperwork-related testing delays. Online ordering ensures all required fields are completed prior to order submission.
- One website to order, track testing in progress, receive results, and manage customer service inquiries.
- Automatically retain an online version of completed test orders and reports.

Set up your new account.

Follow these steps:

1. Visit www.preventiongenetics.com/sponsoredTesting/
2. Find a sponsored testing program and select **MORE INFORMATION**.
3. If online ordering is available, **SELECT** link in upper right corner of the program web page.
4. Then click on **SIGN UP** to create your new account.
5. Follow the **PROMPTS** to enter your information.
6. A verification email* will be sent to **CONFIRM** your email address.
7. **WELCOME** to your ordering portal!

OR **Scan** this code,

OR **Click** here,

https://alnylam.preventiongenetics.com/

to go to our Sponsored Testing web page!

**PreventionGenetics' verification emails may be sent to your spam folder or blocked by your organization's security. To avoid this, add (or reach out to your IT department to add) our notification email address (no-reply@preventiongenetics.com) to your allow list.*

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AlnylamAct

PREVENTIONGENETICS USE ONLY

Test information is available on our website:
PreventionGenetics.com

All testing must be ordered by a qualified Healthcare Provider

THIS FORM MUST ACCOMPANY ALL SPECIMENS

FOR PATIENT SELF COLLECTING A SAMPLE, CHOOSE ONE:
☐ Ship one Saliva GeneFiX™ Saliva Collection kit to patient's address.
☐ Ship one Buccal OCD-100 kit to patient's address.

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PERSON COMPLETING FORM	CONTACT (PHONE AND EMAIL)	DATE OF REQUEST (MM/DD/YYYY)

PATIENT INFORMATION

LAST (FAMILY) NAME	FIRST NAME	MI	DATE OF BIRTH (MM/DD/YYYY)

ADDRESS	CITY	STATE	ZIP

EMAIL	PHONE NUMBER	GEOANCESTRY / ETHNICITY
		☐ Asian ☐ Black/African American ☐ White/Caucasian ☐ Ashkenazi Jewish ☐ Hispanic ☐ Native American ☐ Middle East/North Africa ☐ Pacific Islander ☐ French Canadian ☐ Sephardic Jewish ☐ Mediterranean ☐ Other: _____
MEDICAL RECORD NUMBER (MRN)	SPECIMEN COLLECTION DATE (MM/DD/YYYY) If no collection date is provided, date of receipt will be used.	

SPECIMEN SOURCE	BIOLOGICAL SEX	BLOOD TRANSFUSION	BONE MARROW TRANSPLANT
☐ Blood ☐ Saliva ☐ Buccal	☐ Male ☐ Female ☐ Other _____ SPECIFY KARYOTYPE	☐ NO ☐ Within last 30 days _____ MM/DD/YYYY _____ TYPE	☐ NO ☐ Yes, include date _____ MM/DD/YYYY

HAS PATIENT BEEN TESTED PREVIOUSLY AT PreventionGenetics?
☐ NO ☐ YES, PG ID# _____

ELIGIBILITY CRITERIA

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.

Have a family history OR suspected diagnosis of primary hyperoxaluria (select below):

☐ Family history of primary hyperoxaluria

OR

☐ Adult (18 years or older) with either elevated urinary oxalate OR elevated plasma oxalate

OR

☐ Child (less than 18 years old) with one of the following (please select at least one):
- ☐ Failure to thrive **AND** impaired kidney function
- ☐ Nephrolithiasis
- ☐ Nephrocalcinosis
- ☐ Elevated urinary oxalate **OR** elevated plasma oxalate

CLINICAL HISTORY

Family History

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

RELATIONSHIP TO PATIENT	SELECT	DIAGNOSED CONDITION	AGE AT DIAGNOSIS
	☐ Maternal ☐ Paternal		
	☐ Maternal ☐ Paternal		

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.

Optional Clinical History

Other Clinical Features:
☐ Hematuria or urinary tract infections due to nephrolithiasis
☐ Chronic kidney disease (with nephrocalcinosis)
☐ Kidney failure
☐ History of acute kidney injury
☐ Other: _____

eGFR: _____
Age of onset of first sign/symptom: _____ years
Presenting sign: _____

Biochemical markers (if known): *Patient value / reference range*
☐ Oxalate levels (>ULN)
☐ urinary **or** ☐ plasma _____ / _____

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TEST SELECTION

TEST CODE	TEST NAME	DESCRIPTION
☐ **16029**	**Primary Hyperoxaluria Panel**	*AGXT, GRHPR, HOGA1*
☐ **16035**	**Primary Nephrolithiasis Panel**	*ADCY10, AGXT, ALPL, APRT, ATP6V0A4, ATP6V1B1, ATP7B, BSND, CA2, CASR, CLCN5, CLDN16, CLDN19, CLPB, CYP24A1, FAM20A, FOXI1, GNA11, GPHN, GRHPR, HNF4A, HOGA1, HPRT1, KCNJ1, MAGED2, MOCOS, MOCS1, MOCS2, NHERF1, OCRL, PEX6, PREPL, PRPS1, SLC12A1, SLC22A12, SLC26A1, SLC2A9, SLC34A1, SLC34A3, SLC3A1, SLC4A1, SLC7A9, UMOD, VDR, XDH*
Gene-specific family follow-up testing is available at no additional charge for relatives of program participants who received a Pathogenic/Likely Pathogenic result or approved VUS. Relatives do not need to meet the eligibility criteria listed on page 1 of this form.		
☐ **100**	**Family Follow-Up Testing**	Gene(s): Variant(s) or comments: Proband PGID#: Relationship to Proband: ☐ Parent ☐ Sibling ☐ Grandchild ☐ Child ☐ Other_____

SPECIAL INSTRUCTIONS

SP318

☐ **SPECIMEN COLLECTED IN NEW YORK STATE**
Include New York State Genetic Testing Healthcare Provider Statement and New York State Non-Permitted Laboratory Test Request approval letter if test is not NY state approved. For a list of NY state approved tests, see website.

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 section above. PreventionGenetics will report any Pathogenic/Likely Pathogenic variants found in this patient for the gene(s) ordered.

COMMENTS

GENETIC COUNSELING

Alnylam Pharmaceuticals has partnered with a third-party, Genome Medical, to provide no-cost genetic counseling services to any patient who enrolls in this sponsored testing program. Genome Medical will not disclose any protected health information to any party, including Alnylam Pharmaceuticals, as part of these services. By ordering this test, you are providing PreventionGenetics permission to facilitate the provision of genetic counseling services.

By checking the following boxes, my patient has agreed to allow PreventionGenetics to facilitate the provision of pre-test and/or post-test genetic counseling services by Genome Medical.

☐ **Pre-test** genetic counseling referral to Genome Medical.

☐ **Post-test** genetic counseling referral to Genome Medical.*

*Patients with positive or VUS results will be offered individual genetic counseling. Patients with negative results will be provided with genetic education via a video link.

Genome Medical will contact the patient to schedule their genetic counseling appointment using the phone number and email address provided below.

Email or Phone AND State/Province must be provided for Genetic Counseling.

PATIENT PHONE NUMBER

PATIENT EMAIL ADDRESS

STATE/PROVINCE WHERE PATIENT RESIDES (REQUIRED)

Patients will receive a text message to schedule an appointment if they have SMS texting available on their phone.

If Power of Attorney for medical decisions/ communication is needed, the patient/ family will need to provide documentation to Genome Medical upon scheduling their genetic counseling appointment.

For other questions related to genetic counseling, Genome Medical can be reached at: clinical@genomemedical.com.

PROVIDER CONSENT

By signing below, you, the Healthcare Provider, agree you have obtained the patient's (or parent/guardian's if patient is a minor) informed consent to perform this test in accordance with applicable laws/regulations, including state genetic testing laws, and confirm the patient has been appropriately counseled and understands the risks, benefits, and limitations of this genetic testing and the implications of the results. You further attest that the patient meets the eligibility criteria for the Alnylam Act® program, that the genetic testing is clinically appropriate for the patient, and that you are authorized under applicable state/provincial law to order this test. You warrant that you will not seek reimbursement for this sponsored test from any third party, including but not limited to U.S. federal healthcare programs. You also confirm the patient authorizes PreventionGenetics to use and disclose de-identified patient test data and results ("De-identified Data") to promote research and improve the diagnosis and treatment of the genetic diseases. The De-identified Data may be used for research purposes as well as to facilitate and improve the diagnosis of genetic changes and diseases in other patients. For these reasons, PreventionGenetics may disclose De-identified Data with external physicians, scientists, researchers and Alnylam Pharmaceuticals. No protected health information will be shared. For orders originating in Canada, the patient has been informed that their personal information and specimen will be transferred to and processed in the U.S. As the Healthcare Provider, you hereby authorize PreventionGenetics to share your name, institution, address, and contact information with Alnylam Pharmaceuticals, and consent to Alnylam Pharmaceuticals contacting you. For information about how Alnylam may use your personal data, visit https://alnylampolicies.com/privacy and view Privacy Notice for Healthcare Professionals (General Use). In addition, per applicable law, you may have the right to opt-out of certain uses of your data, and additional rights as detailed in PreventionGenetics privacy policy.

HEALTHCARE PROVIDER SIGNATURE | **PRINTED NAME** | **DATE**

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PROVIDER INFORMATION AND REPORTING

Our preferred method of report transmission is uploading to our secure web portal, myPrevent. Please provide an email address, when possible. If you have additional specific reporting requests, indicate them below.

INSTITUTION

ADDRESS	**CITY**	**STATE**	**ZIP**

REQUESTING PHYSICIAN (First, Last, Degree)	**REQUESTING GENETIC COUNSELOR OR ALLIED PROVIDER** (First, Last, Degree)
EMAIL ADDRESS (For report access via myPrevent)	**EMAIL ADDRESS** (For report access via myPrevent)

PHONE NUMBER	**NPI#**	**PHONE NUMBER**	**NPI#**

IF YOU REQUIRE REPORTS TO BE TRANSMITTED VIA ANOTHER SECURE METHOD, SPECIFY HERE.

LIST ADDITIONAL HEALTHCARE PROVIDERS AND THEIR EMAILS TO ALLOW ACCESS TO REPORTS

INSTITUTIONAL BILLING

BILLING ID	**SPECIAL PROJECT NUMBER**
ALNYLAM10318	**SP318**

SPECIMEN REQUIREMENTS / SHIPPING AND HANDLING INSTRUCTIONS

Label all specimen containers with the patient's name, date of birth, and/or ID number. At least two identifiers should be listed on specimen containers. Specimen deliveries are accepted Monday-Saturday for all specimen types. Holiday schedules will be posted on our website at least one week prior to major holidays.

WHOLE BLOOD
Requirements: Collect 3 ml - 5 ml of whole blood in EDTA (purple top tube) or ACD (yellow top tube), minimum 1 ml for small infants.

Shipping: At room temperature or refrigerated, a blood specimen is stable for up to 8 days. Include a refrigerated gel pack in the shipping container. Fresh blood specimens are preferred.

SALIVA
Requirements: Saliva Collection kit used according to manufacturer instructions. DNA from saliva specimens is invariably contaminated with microbial and food DNA, which can impact specimen quality and may result in delayed testing and/or the need for a second specimen.

Additional instructions to help families collecting samples at home are included in each home saliva kit order.

Shipping: Specimens may be shipped at room temperature.

BUCCAL SWAB (OCD-100 Preferred)
Requirements: OCD-100 Buccal Swab used according to manufacturer instructions. Buccal swabs are most appropriate for targeted, known variant testing. DNA from buccal specimens is invariably contaminated with microbial and food DNA, which can impact specimen quality and may result in delayed testing and/or the need for a second specimen.

OCD-100 instructions are available in about 30 different languages. To request special instructions for patients, add a note in the Comments section of the kit order indicating which language is needed and we will do our best to accommodate. Default instructions are English.

Shipping: At room temperature, an OCD-100 buccal specimen is stable for up to 80 days. Specimens may be shipped at room temperature.

For additional questions or concerns, please contact our Client Service Representatives or our Genetic Counseling Team at (715) 387-0484, or email: support@preventiongenetics.com.

SHIPPING ADDRESS
PreventionGenetics - Diagnostic Lab
3800 S. Business Park Ave.
Marshfield, Wisconsin 54449
USA

Comment SP318