CONSENT FOR GENETIC TESTING AND PARTICIPATION IN SPONSORED TESTING PROGRAM

Summary

My healthcare provider ("Ordering Provider") has ordered the NovoDETECT™ Primary Hyperoxaluria (PH) Panel or NovoDETECT™ Nephrolithiasis (Kidney Stone) Panel (the "Genetic Testing") under the genetic testing program sponsored by Novo Nordisk (the "Program") and provided by Quest Diagnostics ("Quest"). The program is intended to help healthcare providers, and their patients, identify rare genetic diseases of recurrent kidney stones.

The Genetic Testing will be performed by Blueprint Genetics ("Blueprint") in a CLIA-certified clinical DNA testing laboratory located in Helsinki, Finland. Blueprint is a Quest Diagnostics company.

If the Genetic Testing finds one or more genetic variants of unknown significance (indeterminate results) in the genes associated with PH, my healthcare provider will direct me to submit a urine specimen for further testing (the "Urine Testing"). The sample needed for the Urine Testing will be collected by ExamOne®, a Quest Diagnostics company. The Urine Testing will be performed by Quest in a CLIA-certified clinical testing laboratory located in the US, governed by HIPAA.

My healthcare provider may recommend genetic counseling or further testing of myself and/or my family members. Genetic counseling will be provided at no charge to me or my healthcare provider as part of this Program. If my healthcare provider recommends genetic counseling, the genetic counselor and related support team will contact me.

The Genetic Testing, Urine Testing, test-related sample collection, and genetic counseling are paid by Novo Nordisk if I choose to participate in this Program. However, I will be responsible for the cost of my routine office visits and any other costs related to standard of care.

Purpose of this Genetic Testing

The purpose of this Genetic Testing is to identify if you have gene variants that may indicate the presence of an increased risk of developing rare genetic diseases of recurrent kidney stones, or if there is an increased risk of passing a genetic disease onto a child. If the results of the Genetic Testing are of unknown significance, the purpose of the Urine Testing is to test for biomarkers associated with Primary Hyperoxaluria and use the results from this testing to reevaluate the genetic variant(s) of unknown significance. The Genetic and Urine Testing can provide a diagnosis or help provide information for symptom management, treatment, or lifestyle changes. However, genetic testing cannot always determine when or what symptoms of the condition may show, which symptoms will occur first, how severe the condition will be, or how the condition will progress over time.

Description of the Testing

The Genetic Testing analyzes DNA to find any abnormal changes (mutations, also called variants) that might cause disease, make it more likely to develop a disease, and/or increase the chance of having a child affected by a disease. It will look for variants in multiple genes at the same time.

The Genetic Testing will be performed on blood or saliva as decided by you and your Ordering Provider. A blood sample is collected by your Ordering Provider or by ExamOne by inserting a sterile needle into a vein in your arm using a procedure called venipuncture. Your healthcare provider has explained the risks associated with a blood sample collection. A saliva sample is collected by you or your Ordering Provider by swabbing the inside of your cheek with a specially designed DNA collection device. Quest will then use the sample to test for Nephrolithiasis and/or Primary Hyperoxaluria.

If Urine Testing is performed, a urine sample will be collected after the initial results of the Genetic Testing have come back. The urine sample will be collected by you, under the direction of your Ordering Provider or by ExamOne. To complete collection, you will be instructed to urinate into a collection cup. Quest will then use the urine sample to test for biomarkers that help your healthcare providers understand and interpret genetic variants of unknown significance.

No tests other than those authorized shall be performed on the sample(s). More information about Nephrolithiasis and Primary Hyperoxaluria is available from your Ordering Provider and can also be found at Blueprint Genetics' website at https://blueprintgenetics.com/novodetect/.

Possible Results and Significance of the Results

The results of the Genetic Testing and, if performed, Urine Testing could be:

- Positive, and may (i) contribute to the diagnosis of a genetic condition, (ii) reveal carrier status for a genetic condition, (iii) reveal a predisposition or an increased risk for developing a genetic disease in the future, or (iv) have implications for other family members.
- Negative, and may (i) reduce but not eliminate the possibility that your condition has a genetic basis, (ii) reduce but not eliminate your predisposition or risk for developing a genetic disease in the future, (iii) be uninformative, (iv) not remove the need for additional testing.
- Of uncertain significance and may (i) lead to a suggestion that testing additional family members may be helpful, (ii) remain uncertain for the foreseeable future, or (iii) be resolved over time. Your healthcare provider will be notified of any changes to the classification of previously reported variants that relate to your results.

Limitations

Please note that genetic tests are not definitive. Due to limitations in technology or incomplete medical knowledge, some disease-causing variants may not be detected. Therefore, it is not possible to completely exclude all risks for all possible genetic diseases for you and your family members, including your children. Moreover, in some cases, the genetic test may indicate an abnormality in a gene, however, that does not always mean a genetic disorder will manifest. In addition, the genetic test may indicate a genetic abnormality when the individual is actually unaffected (false positive) or may indicate no genetic abnormality when the individual is actually affected (false negative). There may also be possible sources of error including, but not limited to, trace contamination, rare technical errors in the laboratory, rare DNA variants that compromise data analysis, inconsistent scientific classification systems, and inaccurate reporting of family relationships or clinical diagnosis information.

Family Relationship Findings

If several family members are tested, accurate interpretation of the results depends on the information provided concerning familial relationships. In addition, there is a possibility that the genetic test will reveal that the reported familial relationships are not true biological relationships.

Privacy and Confidentiality

In order to perform the genetic test, in addition to the Sample, we will collect certain personal data, including first name, last name, address, date of birth, gender, family relations, disease, symptoms, and medical information ("Personal Data").

You have the right to confidential treatment of your Sample, Personal Data, the results of the Genetic and Urine Testing (the "Results"), and the genetic information generated from the testing ("Genetic Data"). Except as described below, only Quest and Blueprint and their contracted partners will have access to the Sample, Personal Data, Results, and Genetic Data. The Results may also be released to the following person(s): (i) you or your authorized representative, (ii) the ordering healthcare provider, (iii) those authorized in writing, (iv) the patient or their personal representative, and (v) those allowed access to test results by law.

Disclosures to Novo Nordisk

For purposes of this Program, we will share with Novo Nordisk information about your genetic variant(s) and its classification from which all directly identifying information about you has been removed. In addition, to be paid for the materials and services associated with the testing, we will share with Novo Nordisk aggregated statistics about the number of tests performed, collection kits used, and genetic counseling sessions provided. If you do not wish to have this information shared with Novo Nordisk, you cannot participate in the Program. However, if you want Nephrolithiasis and/or Primary Hyperoxaluria testing performed without any information disclosed to Novo Nordisk, your Ordering Provider may order such testing, but it will not be paid for by Novo Nordisk.

Other Uses of Your Data

We also may use and disclose your Genetic Data and other health data for purposes of treatment, payment, and healthcare operations such as: internal operations, statistical analysis, and monitoring and improving our testing and variant classification. We may also share information about your genetic variant and its classification with external databases, used by many labs, that help to improve variant classification and patient care, and we may publicly share aggregated testing and variant statistics (without any direct identifiers) derived, in part, from your testing.

Storage of Your Sample(s) and Data

Personal Data, Genetic Data, and the sample(s) will be stored and protected in strict confidence and in compliance with applicable legal and regulatory obligations, including, for Quest, HIPAA and Quest's Notice of Privacy Practices available at https://www.questdiagnostics.com/our-company/privacy/privacy-notice and, for Blueprint, GDPR and Blueprint's Privacy Notice, available at https://blueprintgenetics.com/privacy/.

The sample(s), Personal Data, and Genetic Data will be retained by Blueprint and Quest in accordance with applicable law and our Data Retention Policy. For example, because our labs are CLIA-certified, we are required to retain your raw genetic data for two years. Samples of residents of the following states will be destroyed within 60 days of the end of the testing processes: Alaska, Delaware, New Hampshire, New Jersey, New Mexico, New York, Oregon.

Implications of Genetic Testing and Your Rights

Your Results may become part of your permanent medical record. In some cases, persons with a genetic diagnosis have experienced problems with health insurance coverage and employment. The U.S. Federal Government has enacted several laws that prohibit discrimination based on genetic test results received by health insurance companies and employers. However, these laws do not apply to life insurance, long-term care insurance, or disability insurance. In addition, these laws prohibit unauthorized disclosure of this information. For more information, you can visit https://www.genome.gov/about-genomics/policy-issues/Genetic-Discrimination.

You have the right to:

- Receive a copy of this consent form signed by you;
- Know the results of the genetic test;
- Withdraw your consent to the genetic test (until it has been performed);
- Inspect and obtain your genetic data from the records we hold about you;
- Request the correction of your genetic data;
- Request the destruction of your sample(s) (as long as it has not been anonymized);
- Until the moment you have been given the test results, the right not to be informed about such results in full or in part;
- For Wyoming residents only, request the destruction of the Results and Genetic Data.

To exercise any of these rights, please contact us at +1 (650) 452-9340 or privacy@blueprintgenetics.com.

Notification of Test Results

Your healthcare provider will provide you with the Results unless you direct otherwise.

Patient Attestation of Informed Consent

By signing this Informed Consent Form, I confirm that I have received, read, and understood the preceding written explanation about genetic testing. I have been adequately informed regarding the purpose, scope, type, and significance of such analysis and its possible results. The responsible physician has informed me about possible prevention/treatment measures of the suspected disease, as well as provided me with alternatives to genetic testing. I understand that genetic testing is voluntary. Furthermore, I confirm that I have had sufficient opportunities to ask questions, and such questions were answered in an understandable manner and to my full satisfaction.

I hereby give consent to Blueprint and Quest to conduct genetic testing for a possible diagnosis of the disease specified above, to the processing of my Personal Data and Genetic Data necessary to perform such testing, and to be informed by my physician of the results of the test.

Patient name (please print):	**Patient date of birth (YYYY-MM-DD):**
Patient signature:	**Date (YYYY-MM-DD):**
Name and relationship of Legal Representative, if patient is a minor (please print):	**Signature of Legal Representative, if patient is a minor:**

Please submit this form, along with your sample, in the kit provided, and mail it using the prepaid shipping label.

For questions, please call NovoDETECT™ at (833) 472-2999 to speak with a Blueprint Genetics support team member.