

# PROSTATE*NOW*<sup>™</sup>

## Next Generation of Hereditary Genetic Testing

### General Information About Genetic Testing

#### Procedure

With your permission, the provider's office will schedule you to come into the office and collect a tube of blood via a routine blood draw (in rare cases, this may require a sample of saliva), which will then be shipped to our testing partner, GoPath Laboratories (Chicago IL). Your provider will also be sending relevant clinical and personal information that is required for accurate interpretation. The genetic material, DNA, from your blood cells will be extracted and then analyzed, looking for changes in the "sequence," also known as "variants". After extraction of your DNA and the testing process is complete, your specimen will be destroyed, or within 60 days after the sample was taken (NY State Law). No other test other than those authorized shall be performed on your sample. A report will be securely delivered to your provider, who will notify you of the results. Once reviewed, your provider will make available to you on requests the results of your testing in accordance with the law.

#### Results



##### POSITIVE:

- I. May explain or contribute to the diagnosis of your cancer
- II. May affect the management of your cancer
- III. May reveal an increased risk for development of future diseases or other cancers
- IV. May have implications to other family members



##### NEGATIVE:

- I. No genetic change or variant has been identified in your DNA that would explain your cancer.
- II. Reduces, but does not eliminate, the possibility that your cancer has a genetic basis or that family members would be free from genetic disorders or cancers in the future as a result of other genes not included in this test.
- III. Does not eliminate the need for additional testing for future cancer diseases or other cancers
- IV. May have implications to other family members



##### INCONCLUSIVE/VARIANT OF UNCERTAIN SIGNIFICANCE (VUS):

- I. A genetic change or variant was identified, but there is insufficient information at this time to determine if it is associated with increased risks to cancer or other genetic diseases.
- II. Further testing and analysis, now and in the future, may be recommended.
- III. Over time, these variants may be resolved or better defined as a direct result of broad based population testing. You may be notified of these clinical updates related to your genetic test.
- III. May reveal an increased risk for development of future diseases or other cancers
- IV. May have implications to other family members



##### UNEXPECTED:

- I. Rare, but may reveal an important genetic change that is not directly related to the reason for your testing but may provide risks for another genetic condition.

### Limitations of this genetic test?

Genetic testing is an important part of the diagnostic process. However, it may not always give a definitive answer. In some cases, testing may not identify a genetic change even though one exists. This may be due to limitations in current medical knowledge or testing technology. Additionally, although rare, inaccurate results may occur for various reasons. These include, but are not limited to: mislabeled samples, inaccurate reporting of clinical/medical information, rare technical errors, or unusual circumstances such as bone marrow transplantation, or the presence of change(s) in such a small percentage of cells that the change(s) may not be detectable by the test (mosaicism).

Accurate interpretation of test results may require knowing the true biological relationships in a family. Failing to accurately state the biological relationships in you/your child's family may result in incorrect interpretation of results, incorrect diagnoses, and/or inconclusive test results. In some cases, genetic testing can reveal that the true biological relationships in a family are not as they were reported, such as non- paternity (the stated father of an individual is not the biological father) and consanguinity (the parents of an individual are related by blood). It may be necessary to report these findings to the health care provider who ordered the test. This test does not have the ability to detect all of the long-term medical risks that you might experience.

### Data Sharing/Storage/Confidentiality

Your sample, test results and relevant clinical information provided (known as "my data") is considered sensitive, confidential and personal, highly subject to strict legal requirements regarding how it can and cannot be used, as well as protected, in full compliance with all Health Insurance Portability and Accountability Act (HIPAA) regulations.

There are federal and state laws that address genetic discrimination and can be found in the U.S. Genetic Information Nondiscrimination Act (GINA). Specifically, this limits the use of these results and discrimination by employers and health insurance companies. However, it does not protect individuals in the military nor possible discrimination by other types of insurance such as life, disability or long-term care.

### De-identified Research and Database Participation

After testing is complete, your sample and data will be de-identified, meaning information that can be used to identify the sample as yours will be removed. The data we gather may be used for test development and improvement, internal validation, quality assurance, and training purposes. DNA specimens are not returned to individuals or to referring health care providers unless specific prior arrangements have been made.

De-identified data can help health care providers and scientists understand how genes affect human health. Though you may not personally benefit, sharing this information helps to provide better care for patients and allows researchers to make discoveries. GoPath shares this information with health care providers, scientists and health care databases. No personal identifiable information will be shared. Instead, your information will be labeled with a unique code.

Even though a code is used for reporting information to the database, there is a low risk that you could be identified based on the data that is shared. GoPath believes that this is unlikely, but the risk is greater if you have already previously shared you/your child's genetic or health information with public resources, such as genealogy websites.

I have received verbal, video and written information from my physician in words that I understood the nature of the genetic testing that I am about to undergo. I understand that specimen(s), such as blood, saliva, cheek swab, dried blood spot, skin biopsy, and/or urine sample, will be taken from me. I understand that the samples will be used for determining if there is a hereditary component to my cancer, I have a genetic disease, a possible carrier of a genetic disease, or are more likely to develop a genetic disease or condition.

The nature of the genetic test, ProstateNow, has been explained to me and the accuracy of the test and its risks and limitations have been detailed. I understand that infrequent errors may occur, even though the likelihood of an incorrect diagnosis or a misinterpretation of the result is extremely small. The likelihood of this occurring has been estimated to be less than 1%. I understand that a negative result reduces, but does not eliminate, the possibility that I carry a mutation(s) in the gene(s) analyzed or in other gene(s) that are not included in the test.

I understand that no test will be performed on my sample other than the one(s) authorized by this consent and my doctor.

Please see the following page for consent and signature.

## Genetic Testing and Release of Information/Payment

I authorize U.S. Urology Partners and GoPath Laboratories to use and release any pertinent and requested information without limitation. I allow access to my medical information provided by my physician to be used by U.S. Urology Partners and GoPath Laboratories for authorization to my health plan and/or insurance provider to directly pay GoPath Laboratories for any services rendered, including and not limited to the use of genetic test results for research purposes.

**\*I understand that I may be financially responsible for up to \$399. The final amount will be determined after your claim has been pre-authorized and processed. (You will receive a courtesy phone call from us notifying you of your coverage.)**

- ☐ **Yes** - I consent to genetic testing and the release of my information.
- ☐ **No - I do not** consent to genetic testing and the release of my information.

## Research Consent

I authorize U.S. Urology Partners and GoPath Laboratories to use my sample for genetic studies. I understand my results will be used for research purposes to further advance clinical findings. I understand I may be contacted by the lab research team for more information. You may contact U.S. Urology Partners and GoPath to opt out of this program at any time.

- ☐ **Yes** - I consent for U.S. Urology Partners and GoPath to use my results for research purposes.
- ☐ **No - I do not** consent for U.S. Urology Partners and GoPath to use my results for research purposes. consent for GoPath to use my results for research purposes.

## Additional Research Participation

Separate from the above, U.S. Urology Partners and GoPath may collaborate with scientists, researchers and medication developers to advance knowledge of diseases and to develop new treatments. If there are opportunities to participate in research relevant to the disorder in your family, and if you have agreed to be re-contacted, U.S. Urology Partners and GoPath may allow your healthcare provider (or if they are unavailable yourself) to be re-contacted for research purposes, such as the development of new tests, medications, or other treatments. Any research that results in medical advances, including new products, tests or discoveries, may have potential commercial value and may be developed and owned by U.S. Urology Partners and GoPath or collaborating researchers. If any individuals or corporations benefit financially from these studies, no compensation will be provided to you/ your child or you/your child's heirs.

- ☐ **Yes** - I consent for U.S. Urology Partners and GoPath to contact me for additional research participation opportunities.
- ☐ **No - I do not** consent for U.S. Urology Partners and GoPath to contact me for additional research participation opportunities.

First Name	Last Name	Date of Birth
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### PATIENT CONSENT

By signing this form, I acknowledge as the patient that I have read the attached informed consent document and that I authorize U.S. Urology Partners and GoPath to perform genetic testing as described. I have been informed that U.S. Urology Partners and/or GoPath may contact my healthcare provider or me about research opportunities in the future. For the insurance bill, I understand and authorize U.S. Urology Partners and GoPath to share information with the designated insurance carrier for reimbursement. I understand that U.S. Urology Partners and/or GoPath will attempt to contact me about out-of-pocket cost potential. If U.S. Urology Partners and/or GoPath is unsuccessful in its attempts to contact me, it will be my responsibility to contact U.S. Urology Partners or GoPath to determine and pay the out-of-pocket cost. More information, including the GoPath Notice of Privacy Policies, is available on GoPath's website: [www.geneticsnow.com](http://www.geneticsnow.com). I consent for U.S. Urology Partners and GoPath to contact me for additional research participation opportunities.

Signature of Patient/Guardian (required)

Date