

## INFORMED CONSENT FOR DNA TESTING TO ASSESS RISK FOR PROSTATE CANCER (ARUP TEST CODE 2003326)

1. With my signature below, I confirm that I am 18 years or older and that I give my informed consent to be tested for genetic risk of prostate cancer using the deCODE ProstateCancer™ test. My signature below constitutes my acknowledgement that the benefits, risks, and limitations of this testing have been explained to my satisfaction by a qualified health care provider.
2. **This test is valid only for men of European Caucasian ancestry and results are NOT informative for other ethnic groups.** Please indicate your ethnicity (mark all that apply).  
☐ African American    ☐ Asian    ☐ European Caucasian    ☐ Hispanic    ☐ Other \_\_\_\_\_
3. A Bode Tech buccal (cheek) swab sample will be collected, from which DNA will be extracted and used to measure variants (changes in the DNA sequence) associated with risk for prostate cancer. The performance characteristics of this test were validated by deCODE Genetics, Inc. This test has not been cleared or approved by the U.S. Food and Drug Administration (FDA); however, FDA approval is not currently required for clinical use of this test.
4. Test results will be reported as the fold risk (or increase/decrease in risk over the general male population risk) to develop prostate cancer. **This test is NOT designed to diagnose prostate cancer, as test results will only estimate the likelihood of developing prostate cancer compared to the general population.** The results of this test are not intended to be used as sole means for patient management or treatment decisions.
  - Results which indicate an increased risk do NOT mean that I will definitely develop prostate cancer. Any reported increase in risk is in addition to the impact of other risk factors (e.g., family history of prostate cancer) for developing prostate cancer. Preventative measures and regular medical screening may facilitate early diagnosis and treatment in individuals at increased risk.
  - Results which do not indicate a significant increase in risk or results which identify a risk lower than that of the general population does NOT mean that I will never develop prostate cancer. Even with a negative result, it is important to follow advice from my physician or other health care provider and take steps to reduce the risk of developing disease. Such steps may include regular medical screening or examinations for prostate cancer.
5. Risk estimates provided by this test are based on the current understanding of risk and genetic risk factors. New information, such as the identification of new genetic variants, may change the current understanding of risk and risk factors for prostate cancer.
6. DNA testing may cause emotional stress and may potentially lead to insurance or employment discrimination. The Genetic Information Nondiscrimination Act (GINA) protects many US citizens from employment and health insurance discrimination based on results of predictive genetic tests. All tests results are released to the ordering health care provider or those entitled to them by state and local laws.
7. Although DNA testing usually yields precise information, several sources of error are possible which include sample misidentification or inaccurate description of the patient's ethnicity. Testing may not be successful due to technical failure.
8. The sample and DNA extracted from the sample will be stored by deCODE genetics only for the time necessary to perform the analysis. My sample and DNA will not be returned to me or the ordering physician/institution. deCODE genetics will dispose of my sample and DNA within one month of delivery of the test results. This test is not part of any research study and no research will be conducted with the DNA sample I provide.
9. DNA testing is a fee-for-service test. I will be responsible for payment after testing has begun, even if I decide not to receive results.
10. Genetic counseling by a genetic counselor, a physician, or other health care professional is recommended prior to, as well as following, genetic testing.

\_\_\_\_\_  
Patient Printed Name

\_\_\_\_\_  
Patient Signature

\_\_\_\_\_  
Date

**Physician/ Genetic Counselor Statement:** I have explained the DNA testing described above and its limitations to the patient and answered this person's questions.

\_\_\_\_\_  
Physician/ Counselor Printed Name

\_\_\_\_\_  
Physician/ Counselor Signature

\_\_\_\_\_  
Date