Answers to Important Questions

What will the test results provide? Test results alone cannot be used to determine risk of developing prostate cancer. Clinical assessment of family history and other risk factors should be considered in determining a patient’s overall risk.

Is the test useful for all men? The 27 SNPs tested have been validated only for men of European Caucasian descent. Validation was performed in multiple populations of patients of Caucasian descent having confirmed high-grade and intermediate-grade prostate cancer and compared with results of control populations of over 30,000 across the United States and Europe. The SNPs assessed by this test represent most of the identified variants contributing to prostate cancer risk, and only the SNPs listed in the test description will be reported.

Where and how is the test performed? The test is performed by deCODE Genetics Diagnostics Laboratory in Reykjavik, Iceland. Test results are returned to the physician by ARUP Laboratories in Salt Lake City, Utah. The methodology is polymerase chain reaction (PCR) followed by fluorescent primer/probe hybridization (Centaurus™ genotyping method from Nanogen, Inc.) to detect the 27 common SNP DNA markers identified as prostate cancer risk markers. (Rare diagnostic errors may occur due to mutations at binding sites of primers or detection probes).

What is the required specimen? Two buccal (cheek) swabs per patient are required. The cost of the collection kit is included in the test price, and the kit will be provided through the ordering physician.

How long will it take to get results? Results will be available 8–16 days after the specimen is received at ARUP.
Intended Purpose of the Test
This test provides a personalized genetic risk assessment for the development of prostate cancer in European Caucasian men regardless of family history of prostate cancer. Only the genetic risk for prostate cancer is reported. This test has no relationship to the deCODEme™ genetic scan products offered by deCODE Genetics that assess genetic contribution to multiple disorders/traits.

What the Test is NOT
The deCODE ProstateCancer™ test does not provide a deterministic prognosis of developing prostate cancer. The result is an assessment of a man’s genetic susceptibility for developing prostate cancer (analogous to LDL cholesterol for assessing risk for cardiovascular disease). The test reports two risk values—a genetic risk relative to the general population and a lifetime risk of developing prostate cancer. Patients should understand that a high-risk result is not a guarantee of developing prostate cancer and a low-risk result is not a guarantee of never developing prostate cancer.

The test does not diagnose or confirm existing prostate cancer. The result reported is not indicative of prostate cancer (analogous to a low cholesterol level not indicating heart disease).

The test is not valid for all ethnic groups. All markers tested are controls used to validate the genetic risk.

The test is not available to the general public. The deCODE ProstateCancer™ Genetic Risk Assessment test must be ordered by a physician, and the test results will be returned to the ordering physician. ARUP does not offer tests directly to the general public.

The test is not validated for all ethnic groups. All markers tested are controls used to validate the genetic risk.

The test is helpful for men with no family history of prostate cancer. This test assesses genetic risk regardless of family history of prostate cancer, and the results reported are independent (multiplicative) to the risk conferred by family history.

Locus SNP Genotype Relative Risk Population Frequency Number of Cases/Controls
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MSMB rs10903994 CC CC CC 5,000/5,000
POUMS rs17109198 CT CT CT 16,229/14,821
3p12 rs10207654 TT TT TT 13,373/10,798
11q13 rs10994494 TT TT TT 13,373/10,798
SLC22A3 rs9364554 CT CT CT 7.370/5.742
LMIK2 rs4666567 CT CT CT 7.370/5.742
TCF2 rs4340796 AA AA AA 3.500/14,000
3p12 rs2660753 CC CC CC 7.370/5.742

References