NEOVARE™
PERSONALIZED DIAGNOSTICS
by siParadigm
Hereditary Cancer Risk Assessment Test

Name:
DOB: ID#:
Sex: Requisition #:

ORDERING PHYSICIAN	SPECIMEN	
Name:	Case#:	
Facility:	Collected:	Received:
Phone:	Final Report:	
Fax:	Specimen Type:	
Address:	Your #:	

NEGATIVE RESULT (NO PATHOGENIC MUTATIONS ARE IDENTIFIED)

INTERPRETATION

A negative result means no pathogenic or likely pathogenic variants linked with an increased risk of developing hereditary colorectal, gastric, melanoma, prostate, pancreatic or renal cancers were identified in the 43-genes-panel in addition to *BRCA1 and BRCA2*. See the method and limitations section for test limitations.

DISCLAIMER

The negative result does not exclude the risk of developing cancer. It only means that your risk is not expected to be above the average risk of the population due to a genetic change in these genes. Other risk factors that are not accounted for by this test are non-genetic risk factors such as, but not limited to, lifestyle and environmental as well as familial risk factors that have no known genetic association. To better understand your risk, you can speak to one of our genetic counselors at no charge (see below). See the method and limitations section for test limitations.

INDICATION FOR TESTING

- Patient was diagnosed with prostate cancer at age 56.
- Sister was diagnosed with breast cancer at age 43.

GENES ANALYZED

APC	*CDH1*	*MLH1*	*PALB2*	*RET*
ATM	*CDK4*	*MRE11A*	*PDGFRA*	*SDHA*
AXIN2	*CDKN2A*	*MSH2*	*PMS2*	*SDHB*
BAP1	*CHEK2*	*MSH3*	*POLD1*	*SDHC*
BARD1	*EPCAM*	*MSH6*	*POLE*	*SDHD*
BMPR1A	*HOXB13*	*MUTYH*	*PTEN*	*SMAD4*
BRIP1	*KIT*	*NBN*	*RAD50*	*STK11*
BRCA1	*MEN1*	*NF1*	*RAD51C*	*TP53*
BRCA2	*MITF*	*NTHL1*	*RAD51D*	*VHL*

SIGNED BY

Sherif A. Nasr, MD, FCAP

Genetic counselors are available for healthcare providers to further discuss this result. To refer your patient for genetic counseling through Neovare, please call 844-NEOVARE (636-8273) or visit us at www.neovare.com

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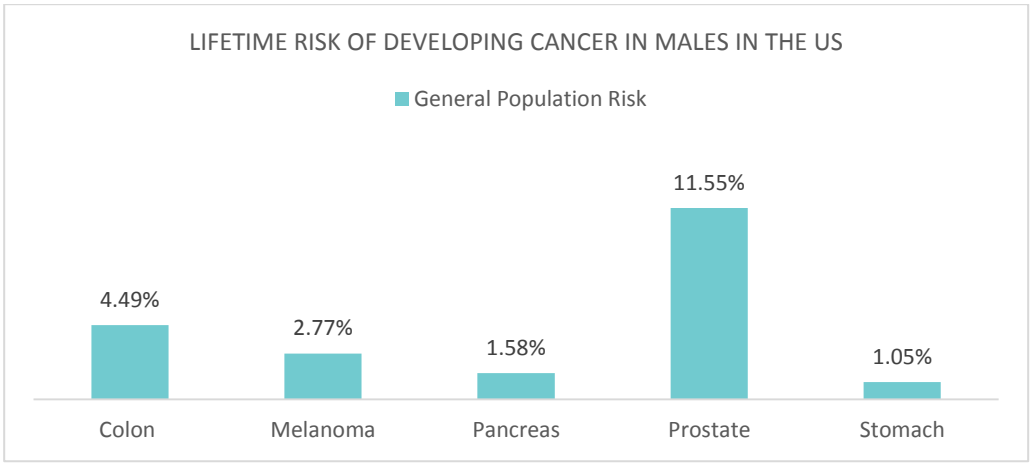

Epidemiology and End Results (SEER) Database and is based on incidence and mortality data for the United States from 2012 through 2014, the most current years for which data are available.

GENERAL CANCER SCREENING GUIDELINES

PROSTATE CANCER

PSA every 2-4 years starting at age 45 and every 1-4 years starting at age 75.

Baseline DRE at 45years and frequency determined according to PSA level.

Prostate biopsy in indicated patients.

COLON CANCER

Colonoscopy every 10 years, or flexible sigmoidoscopy every 5-10 years or CT colonography every 5 years.

Stool-based testing (high-sensitivity, guaiac-based, or immunochemical based) every year, or DNA testing every 3 years.

Healthy diet with plenty of vegetables and fruits.

SKIN CANCER

Limit exposure to UV light, wear protective sun glasses, apply sun screen.

Report any new, unusual, or changing moles to your doctor.

LUNG CANCER

Avoid all forms of smoking.

Maintain a healthy active lifestyle.

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METHOD & LIMITATIONS

Genomic DNA was extracted from this patient's whole blood or saliva sample. Amplification of targeted regions was performed using hereditary custom panel of 651 amplicons that target 43 genes and Oncomine BRCA1 & BRCA2 panel. Next generation sequencing was performed on the Ion S5 machine and analyzed with the Torrent Suite and Ion Reporter Software. GRCh37/Hg19 was used as reference for analysis, which can be found @ http://www.ncbi.nlm.nih.gov/refseq/rsg/.

The mutation nomenclature is based on the convention recommended by the Human Genome Variation Society (http://www.hgvs.org/mutnomen/).

Limitations: This testing is validated to detect germline variants in the coding exons and parts of introns flanking each exon of the BRCA1 and BRCA2 genes in addition to coding exons of 43 additional genes. Genes covered are not all sequenced in their entirety. This technology cannot reliably detect variants at coverage below 100x. Clarity of the call is assessed by multiple factors, including but not limited to number of reads, ratio of variant call to normal allele, if reads are bidirectional or unidirectional, existence of pseudogenes, and the genetic complexity of the region. In such cases confirmation of variants may be performed by Sanger sequencing. Copy number variants are assessed for BRCA1 and BRCA2 using the Oncomine BRCA1&2 panel and are reported based on the quality of the call. In some cases, confirmation by multiplex ligation-dependent probe amplification (MLPA) may be performed. Copy number variants for the other 43 genes are not tested. This test is designed to detect germline variants and is not intended to reliably detect somatic changes or low-level mosaicism. Individuals undergoing genetic testing should understand that rare diagnostic errors may occur. Possible sources of diagnostic errors include genotyping errors. Common examples of genotyping errors include: trace contamination of PCR, rare genetic variants which interfere with analysis, and mosaicism at levels below standard detection. This technology cannot reliably detect large insertions and deletions (>20bp), repeat expansions, or methylation status. All variants are classified according to the ACMG/AMP guidelines (PMID: 25741868). Variants classified as benign or likely benign are not reported. Sequencing results should be used in the context of available clinical information and should not be the sole basis for patient management and treatment. Interpretation of genetic variants is limited by the information available at the time of reporting and the clinical information provided with the sample. The classification and understanding of genetic variants may change over time as new information becomes available. Periodic review of the literature is recommended. Furthermore, negative results cannot eliminate the possibility of hereditary cancer.

CPT CODES

81162, 81408, 81405, 81292, 81298, 81314, 81317, 81321

ICD-10 CODES

C61 and Z80.3.

End of report.