CellMax

DNA Genetic Cancer Risk Test

Test Report

CellMax Life

Test Report

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DNA Genetic
Cancer Risk Test

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1-1. Customer Information

CellMax Sample ID	CL9-0001
Customer First Name	Toni
Customer Last Name	Montana
Date of Birth	xx/xx/xxxx
Gender	☐ M ☒ F
Customer Phone Number	(xxx) xxx-xxxx
Customer E-mail	xxxx@email.com
Name of Authorizing Physician	Dr. Alejandro Sosa
Date of Sample Receiving	xx/xx/xxxx
Date of Report	xx/xx/xxxx

Test Report

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1-2. Test Report Summary

Summary Result: Negative

No Clinically Significant Genetic Mutations Detected

Gene	Mutation	Interpretation

The classification and interpretation of all variants identified in the test reflects the current state of scientific and medical understanding at the time the report is generated. The five variant classification categories include pathogenic, likely pathogenic, variant of uncertain significance (VUS), likely benign, and benign. CellMax Life only reports pathogenic variants, which have strong lines of evidence associated with increased cancer risk. A summary of all variants found can be provided for each patient upon request by their physician for an additional charge.

A positive test result for a pathogenic mutation in a gene means that your lifetime risk(s) of developing the associated cancer(s) is significantly higher than an individual who does not have a mutation. **It does not mean that you have cancer or that you will eventually develop cancer in your lifetime.** Likewise, a negative result **does not mean that you do not have cancer, or that you will not develop cancer at some point in your lifetime.**

Comments

Electronic Signatures

Lab Supervisor
Narendra Desai, CLS MTA00037776

Date

CellMax Life

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1-3. List of Cancers / Tumors Tested

Cancer / Tumor	Gene(s) Correlation	Pathogenic Gene Mutation Detected
Breast	*ATM, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, NBN, NF1, PALB2, PPM1D, PTEN, RAD51C, STK11, TP53*	No
Ovaries	*BRCA1, BRCA2, BRIP1, DICER1, EPCAM, MLH1, MSH2, MSH6, PALB2, PMS2, PPM1D, RAD51C, RAD51D, STK11, TP53*	No
Endometrium (Uterine)	*EPCAM, MLH1, MSH2, MSH6, PMS2, PTEN, STK11, TP53*	No
Myometrium (Uterine)	*FH*	No
Prostate Gland	*BRCA1, BRCA2, CHEK2, HOXB13, NBN, TP53*	No
Stomach	*APC, BMPR1A, CDH1, EPCAM, KIT, MLH1, MSH2, MSH6, PMS2, SMAD4, STK11*	No
Large Bowel and Rectum (Colorectal)	*APC, BLM, BMPR1A, CDH1, CHEK2, EPCAM, KIT, MLH1, MSH2, MSH6, MUTYH, PMS1, PMS2, PTEN, SMAD4, STK11, TP53*	No
Lung and Pleura	*BAP1, DICER1, EGFR*	No
Small Intestines	*KIT, MLH1, MSH2, MSH6, SDHB, SDHC, SDHD, STK11*	No
Esophagus	*FANCA, FANCB, FANCC, FANCD2, FANCE, FANCF, FANCG, FANCI, FANCL, FANCM, RHBDF2*	No
Urinary Tract and Bladder	*HRAS, MLH1, MSH2, MSH6*	No

1-3. List of Cancers / Tumors Tested

Cancer / Tumor	Gene(s) Correlation	Pathogenic Gene Mutation Detected
Exocrine Pancreas	*APC, ATM, BMPR1A, BRCA1, BRCA2, CDK4, CDKN2A, EPCAM, MLH1, MSH2, MSH6, PALB2, PMS2, SMAD4, STK11, TP53*	No
Endocrine Pancreas	*MEN1, NF1, VHL*	No
Kidneys	*BAP1, BUB1B, CEP57, DICER1, DIS3L2, FH, FLCN, MET, PTEN, SDHB, SDHC, SDHD, SMARCB1, TSC1, TSC2, VHL, WT1*	No
Cervix	*STK11*	No
Skin	*BAP1, CDK4, CDKN2A, DDB2, ERCC2, ERCC3, ERCC4, ERCC5, NF2, PTEN, TP53, XPA, XPC*	No
Bone	*EXT1, EXT2, RECQL4, TP53*	No
Thyroid Gland	*APC, CHEK2, DICER1, MEN1, PRKAR1A, PTEN, RET, TP53*	No
Liver	*APC, HNF1A*	No
Soft Tissue	*RB1, WRN*	No
Miscellaneous Endocrine Glands	*CDC73, FH, MAX, MEN1, RET, SDHAF2, SDHB, SDHC, SDHD, TMEM127, VHL*	No
Blood	*CEBPA, GATA2, PRF1, RUNX1, SBDS*	No

1-3. List of Cancers / Tumors Tested

Cancer / Tumor	Gene(s) Correlation	Pathogenic Gene Mutation Detected
Head and Neck	*CDK4, CYLD, FANCA, FANCB, FANCC, FANCD2, FANCE, FANCF, FANCG, FANCI, FANCL, FANCM, SLX4*	No
Central Nervous System	*AIP, APC, CDKN1C, CDKN2A, DICER1, GPC3, MLH1, MSH2, MSH6, NBN, NF2, PMS2, PRKAR1A, PTCH1, PTEN, SMARCA4, SMARCB1, SUFU, TP53, TSC2*	No
Peripheral Nervous System	*ALK, EZH2, FH, NF1, NF2, NSD1, PHOX2B, SDHAF2, SDHB*	No

SECTION 2

2-1. About the Test

2-2. References

2-1. About the Test

CellMax Life has developed a next-generation sequencing-based test for identifying hereditary cancer susceptibility mutations. The test uses advanced next-generation sequencing (SMSEQ™) targeting approximately 220 kbp of the human genome across 98 genes with a high-degree of analytical sensitivity and specificity. Validation using industry standard methods yielded an accuracy of >99.99%. The genetic panel was curated by a team of genetic specialists to include 98 genes reported in the literature as being associated with increased risk for 25 cancers.

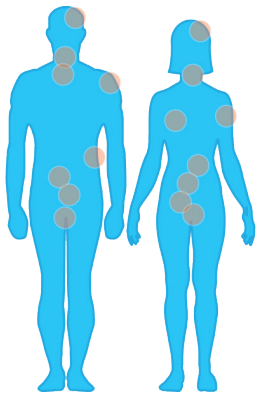
This test was developed and its performance characteristics determined by CellMax Life, a clinical laboratory certified under Clinical Laboratory Improvement Amendments (CLIA #05D2119032) to perform high-complexity testing. It has not been cleared or approved by the FDA. This test is used for clinical purposes, and should not be regarded as investigational or for research.

Genes Tested

AIP	*ALK*	*APC*	*ATM*	*BAP1*	*BARD1*	*BLM*	*BMPR1A*	*BRCA1*
BRCA2	*BRIP1*	*BUB1B*	*CDC73*	*CDH1*	*CDK4*	*CDKN1C*	*CDKN2A*	*CEBPA*
CEP57	*CHEK2*	*CYLD*	*DDB2*	*DICER1*	*DIS3L2*	*EGFR*	*EPCAM*	*ERCC2*
ERCC3	*ERCC4*	*ERCC5*	*EXT1*	*EXT2*	*EZH2*	*FANCA*	*FANCB*	*FANCC*
FANCD2	*FANCE*	*FANCF*	*FANCG*	*FANCI*	*FANCL*	*FANCM*	*FH*	*FLCN*
GATA2	*GPC3*	*HNF1A*	*HOXB13*	*HRAS*	*KIT*	*MAX*	*MEN1*	*MET*
MLH1	*MSH2*	*MSH6*	*MUTYH*	*NBN*	*NF1*	*NF2*	*NSD1*	*PALB2*
PHOX2B	*PMS1*	*PMS2*	*PPM1D*	*PRF1*	*PRKAR1A*	*PTCH1*	*PTEN*	*RAD51C*
RAD51D	*RB1*	*RECQL4*	*RET*	*RHBDF2*	*RUNX1*	*SBDS*	*SDHAF2*	*SDHB*
SDHC	*SDHD*	*SLX4*	*SMAD4*	*SMARCA4*	*SMARCB1*	*STK11*	*SUFU*	*TMEM127*
TP53	*TSC1*	*TSC2*	*VHL*	*WT1*	*WRN*	*XPA*	*XPC*	

Cancer / Tumor Risks Tested

Breast	Ovaries	Endometrium, Uterine
Myometrium, Uterine	Prostate Gland	Stomach
Large Bowel and Rectum	Lung and Pleura	Small Intestines
Esophagus	Urinary Tract and Bladder	Exocrine Pancreas
Endocrine Pancreas	Kidneys	Cervix
Skin	Bone	Thyroid Gland
Liver	Soft Tissue	Miscellaneous Endocrine Glands
Blood	Head and Neck	Central Nervous System
Peripheral Nervous System		



Details About Mutations and Variants

Genetic Variants

All persons carry genetic variants inherited from their parents. A variant can be used to describe a change in a DNA sequence that may be pathogenic, likely pathogenic, unknown significance, likely benign, or benign. Most variants do not cause an increase in the risk of cancer or other disease. The classification and interpretation of all variants identified in the test reflects the current state of scientific and medical understanding at the time the report is generated. Variants are classified by pathogenicity by taking into account the reported variant, and the allelic frequencies from population studies and clinical databases (e.g. 1000 Genomes, ClinVar). A positive test result indicates that an individual has inherited a pathogenic mutation in specific genes and, therefore, has an increased risk of developing certain cancers. It is important to understand that a positive test result does not necessarily mean that the individual will actually develop cancer over their lifetime. Some individuals who inherit pathogenic mutations will never develop the associated cancer(s). A negative test result indicates that an individual has not inherited a pathogenic mutation in any of the genes tested, but does not eliminate the lifetime risk of developing certain cancers.

Pathogenic Variants

Certain mutations in certain genes are associated with an increased risk for cancers and/or hereditary syndromes. These mutations are associated with the potential to alter medical intervention. A pathogenic variant directly contributes to the development of cancer. The variant has strong lines of evidence that associates it with significantly increased cancer risk and necessary clinical action.

Likely Pathogenic Variants

A likely pathogenic variant is very likely to contribute to the development of cancer. The variant has fewer strong lines of evidence that associates it with significantly increased cancer risk.

Uncertain Significance Variants (VUS)

A variant of uncertain significance does not have enough information at this time to support a more definitive classification. There is insufficient evidence to determine if the variant is associated with increased cancer risk.

Likely Benign

A likely benign variant is not expected to have a major effect on cancer. However, additional evidence is needed to confirm this assertion.

Benign

A benign variant has strong lines of evidence that does not associate it with an increased cancer risk.

Test Limitations

Inherited mutations in certain genes are associated with hereditary cancer syndromes or increased risk to various cancer types. The test interrogates and reports single nucleotide variants, insertions, and deletions in genomic DNA. Large scale genomic rearrangements, copy number variants, as well as structural changes are not detected. CellMax Life only reports pathogenic variants, which have strong lines of evidence associated with increased cancer risk.

A negative test result means that the laboratory did not identify a variant that is of pathogenic significance in any of the genes under consideration. This result can indicate that a person is not a carrier of a specific genetic mutation, or does not have an increased risk of developing a certain disease. It is possible, however, that a disease-causing genetic alteration was missed because many tests cannot detect all genetic changes that can cause a particular disorder. Even with genetic sequencing, mutation detection is not 100% sensitive, since sequencing will not detect large genomic rearrangements and large indels. A negative test result, therefore, does not completely rule out the possibility that the patient is a mutation carrier. Further testing may be required to confirm a negative result.