

CellMax

DNA Genetic Cancer Risk Test

TEST DESCRIPTION

The CellMax Life DNA Genetic Cancer Risk Test uses a simple saliva sample to analyze 98 genes (Figure 1) that are associated with 25 different hereditary cancers (Figure 2).

AIP	ALK	APC	ATM	BAP1	BARD1	BLM	BMP1A	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	FANGC	FANCI	FANCL	FANCM	FH	FLCN
GATA2	GPC3	HNF1A	HOXB13	HRAS	KIT	MAX	MEN1	MET
MLH1	MHS2	MSH6	MUTYH	NBN	NF1	NF2	NSD1	PALB2
PHOX2B	PMS1	PMS2	PPM1D	PRF1	PRKARIA	PTCH1	PTEN	RAD51C
RAD51D	RB1	RECQL4	RET	RHBDP2	RUNX1	SBDS	SDHAF2	SDHB
SDHC	SDHD	SLX4	SMAD4	SMARCA4	SMARCB1	STK11	SUFU	TMEM127
TP53	TSC1	TSC2	VHL	WT1	WRN	XPA	XPC	

Figure 1: The 98 genes included in the CellMax Life DNA Genetic Cancer Risk Test. Genes associated with hereditary cancer syndromes and cancer risk were included when there was sufficient evidence in the literature that mutations in those genes greatly affects cancer risk.

About 5-10% of all cancers are hereditary. Through genetic testing, inherited mutations and their associated increased risk of developing specific cancers can be identified. The individual and their physician can create a personalized cancer prevention program based from the test results to guide implementation of additional screening, surveillance, and lifestyle changes. This allows the individual to prevent cancer entirely, or to help identify cancer at an earlier, more treatable stage.

Individuals with cancer can also benefit from genetic testing by knowing if the cancer is due to an inherited mutation, identifying family members that may be at risk, and understanding their possible risk for other cancers.

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		

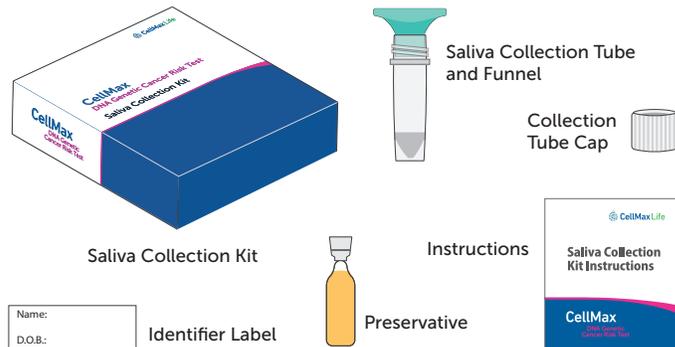
Figure 2: The CellMax Life DNA Genetic Cancer Risk Test identifies increased lifetime risk for 25 different hereditary cancers.

Turnaround time for results is typically 3-4 weeks. All CellMax Life tests are physician ordered and reviewed.

SPECIMEN REQUIREMENTS

Specimen type	Saliva
Container	1 CellMax Life Saliva Collection Kit P/N: cml0001dna
Sample amount	2 mL of freshly collected saliva in collection tube (liquid only, no bubbles)
Storage	In biohazard bag; room temperature at 15-30 °C
Storage stability	Recommended saliva stability with DNA preservative added is 1 month
Special notes	Not recommended for individuals that have undergone a recent bone marrow transplant

KIT CONTENTS



ANALYTICAL PERFORMANCE

CellMax Life's DNA Genetic Cancer Risk Test uses next-generation sequencing to analyze the coding sequences and splice-sites of the 98 genes. Three sets of gold standard reference samples and data (Platinum Genomes, GIAB, and Personal Genome Project) run over several different library preparations were used to analytically validate the end-to-end sample process and data analysis for the test.

	Variant Present	Variant Not Present	Result
Variant Detected	1841 true positives	0 false positives	99.95% Sensitivity
Variant Not Detected	1 false negative	3,898,611 expected reference calls	100% Specificity 99.99% Accuracy

TEST INTERPRETATION

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. CellMax Life only reports pathogenic variants, which have strong lines of evidence associated with increased cancer risk.

Positive Test Result

A positive test result means that a pathogenic mutation was identified in a specific gene that increases the individual's lifetime risk of developing certain cancer(s) compared to those that do not have the mutation. The mutation was inherited from one or both of the individual's parents. A positive result **does not mean that the individual has cancer or will eventually develop cancer in his or her lifetime.**

Negative Test Result

A negative test result means that no pathogenic mutations associated with an increased lifetime risk of developing certain cancers were identified in the genes analyzed. A negative result **does not mean that the individual does not have cancer or will not develop cancer at some point in his or her lifetime.**

Test Limitations

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 summary of all variants found can be provided upon request by the ordering physician for an additional charge. 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.