Product Note
Ordering in Patient Management

LIVEWELLTESTING.COM

CellMax Life

CellMax
DNA Genetic Cancer Risk Test

PATIENT TESTING FOR INHERITED MUTATIONS

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*	*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	*MHS2*	*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*	

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 [1, 2, 3]. Through genetic testing, inherited mutations and their asscociated 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 [4, 5].

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 [6, 7].

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

To place an order, or if you have any questions please contact Max Calcaterra at mcalcaterra@livewelltesting.com

1. Nagy, Rebecca, Kevin Sweet, and Charis Eng. "Highly penetrant hereditary cancer syndromes." Oncogene 23.28 (2004): 6445.
2. Solomon, Sheila, et al. "Inherited pancreatic cancer syndromes." Cancer Journal (Sudbury, Mass.) 18.6 (2012): 485.
3. Hornedo, Emiliano, Javier Benitez, and José Palacios. "The pathology of hereditary breast cancer." Hereditary cancer in clinical practice 2.3 (2004): 131.
4. Kohlmann, Wendy, and Stephen A. Gruber. "Lynch syndrome." (2014).
5. Petrucelli N, Daly MB, Feldman GL. BRCA1 and BRCA2 Hereditary Breast and Ovarian Cancer. 1998 Sep 4 [Updated 2013 Sep 26]. In: Pagon RA, Adam MP, Ardinger HH, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-
6. Moyer, Virginia A. "Risk assessment, genetic counseling, and genetic testing for BRCA-related cancer in women: US Preventive Services Task Force recommendation statement." Annals of internal medicine 160.4 (2014): 271-281.
7. Tung, Nadine, et al. "Frequency of mutations in individuals with breast cancer referred for BRCA1 and BRCA2 testing using next-generation sequencing with a 25-gene panel." Cancer 121.1 (2015): 25-33.

KIT CONTENTS

Saliva Collection Kit

Saliva Collection Tube and Funnel

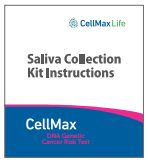
Collection Tube Cap

Name:
D.O.B.:

Identifier Label

Preservative

Instructions



ANALYTICAL PERFORMANCE

CellMax Life's DNA Genetic Cancer Risk Test uses next-generation sequencing to analyze the coding sequences and spice-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** **100% Specificity**
Variant Not Detected	1 false negative	3,898,611 expected reference calls	**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.