Jane Doe
DOB: 1985-01-05

Sample ID: PX947618

Hello Jane,

Thank you for ordering your Kailos test for Cancer Predisposition. Kailos Genetics is committed to making gene-based healthcare available to YOU. We're thankful for your business and we're here to help. If you have any questions, please contact a Kailos Test Consultant at 1-866-833-6865. You can also contact us through our website at www.KailosGenetics.com.

Your Kailos Test Results

Everyone carries DNA changes, known as variants. Following sequencing of your DNA, these variants are analyzed for their effect on your risk of developing cancer. Those that are known to increase your risk are reported in the section below.

If you provided a doctor's name during your registration process, then she/he has received a copy of this report. Your doctor can help you further understand your risks and, if necessary, you can develop an effective monitoring plan. Additionally, Kailos Genetics' counselors are available to speak with you regarding your results by calling 1-866-833-6865.

VARIANTS OF KNOWN CLINICAL SIGNIFICANCE

Clinical Significance	Gene	Variant	Associated With
Pathogenic	BARD1	NC_000002.11:g.215645386G>C	Multiple types of cancer including familial breast cancer

Recommendations

If you have a variant indicated above, this indicates that you have a gene change that increases your risk for one or more cancers. This does NOT mean that you have cancer. Knowing about an increased risk for cancer can allow you to make changes to your screening (i.e. mammograms, colonoscopies) and medical management plan to reduce the chance of cancer developing, or catch a cancer early at a more treatable stage.

Consultation with a genetic counselor, who has training and experience in cancer genetics, is strongly recommended. Topics of discussion should include: (1) cancer risks and other disease risks, (2) type and frequency of cancer surveillance, (3) cancer prevention options and strategies, and (4) the impact of this result on the potential cancer risks for family members. Prior to this consultation, you can view an information video on what it means to have variants that increase cancer risks. This can be viewed at www.kailosgenetics.com.

In addition, information about cancer surveillance and prevention options that can be recommended to an individual with a genetic risk for cancer can be found on the following websites:

National Society of Genetic Counselors: www.nsgc.org
National Cancer Institute: www.cancer.gov/cancerptopics/prevention

Is everything identified by sequencing reported?

Kailos utilizes up-to-date information on DNA variants that increase cancer risk found at the National Institutes of Health. This information increases continually and your report reflects the current state of knowledge at the time of reporting. Since we all have changes in our DNA and most of these do not affect our risk of developing cancer, your report lists only those variants that are thought to increase cancer risk and/or impact medical management. As of the date of this report's publication:

- We do not report benign and likely benign variants, as these variants most likely do not cause an increased cancer risk.
- Also, variants of uncertain significance (VUS) are not reported, as they would not be used to change medical management.

What was tested?

High-throughput sequencing is used to analyze all or part of these genes: ATM, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, EPCAM, MLH1, MRE11A, MSH2, MSH6, NBN, PALB2, PMS2, PTEN, RAD50, RAD51C, RAD51D, RINT1, TP53 and XRCC2. The DNA sequences are compared to a reference standard to determine changes known as variations. These variations may not be detected in areas of lower sequence coverage. Some single-base changes (SNPs), small insertions or deletions and duplications may not be detected. Additionally, some small insertions and deletions may not be as accurately determined as single-base changes.

In an unknown number of cases, nearby genetic variants may interfere with base variant detection. Other possible sources of error include sample mix-up, trace contamination, bone marrow transplantation, and technical errors. The Kailos test does not fully address all inhereited forms of cancer risk. A family history of cancer may warrant additional evaluation. Furthermore, not all mutations will be identified in the genes analyzed and additional testing may be beneficial for some customers.

It’s important to know that a genetic change related to hereditary cancer does NOT mean you have cancer—or that you will definitely get cancer. It means, simply, that your risk is increased.

Legal Notices

This Kailos test can be used by your treating physicians to direct your medical care. That means this test was performed in a CLIA-certified genetic testing facility as follows:

Kailos Genetics CLIA facility (CLIA#: 01D2016114)
601 Genome Way, Suite 2005
Huntsville, AL 35806

CLIA Lab Manager & Supervisor: Michele R. Erickson-Johnson, PhD, MB (ASCP)CM

Medical Director: Ronald McGlennen, MD, FCAP, FACMG, ABMG

All tests designed and implemented by the Kailos Genetics team are of the highest possible quality. Your Kailos test has been validated and performed using quality laboratory processes:

- Primary methodology: Next Generation Sequencing (NGS) enriched by OD-PCR.
- Sequencing methodology: Patient samples and positive and negative controls are sequenced using a MiSeq (Illumina). Sequences are analyzed with Kailos Blue Software. The analysis utilizes the latest DNA alignment, base calling and variant reporting algorithms such as BWA and GATK.