Client Name	Accession No.
TEST CLIENT **6000A Pelham Rd.** **Greenville, SC 29715**	**XXXXXX** Report Status **COMPLETE** Printed Date/Time

Premier Medical LABORATORY SERVICES
6000A Pelham Road, Greenville, SC 29615
Phone: 877-335-2455 Fax: 877-889-9157
http://www.premedinc.com
CLIA ID#: 42D2017829 COLA#: 22873

Patient Name	Patient ID No.	Patient Phone	Date of Birth	Age	Sex
TEST PATIENT			10/14/2002	14	F
Physician	**Date/Time Collected**	**Date/Time Received**	**Date/Time**		
TEST PHYSICIAN					
Comment					

TEST NAME	WITHIN RANGE	OUTSIDE RANGE	REFERENCE RANGE	UNITS
Hereditary Cancer Assessment				

The information presented on this report is provided as supplementary health information. The results presented are intended for use by a physician or other healthcare professional to advise a patient on their health care. This test is not a 501k cleared test, but managed by CMS and FDA under the Clinical Laboratory Improvement Amendment (CLIA) as a LDT. The ordering physician is responsible for the diagnosis and management of disease and decisions based on the data provided. Results are dependent on adequate specimen collection and processing.

Genetic testing was performed in the Dynix Diagnostics CLIA facility at 2260 N US Highway 1; Ft. Pierce FL. 34946. CLIA#: 01D2117185. Medical Director: TEST PHYSICIAN

Results

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

CLINICAL SIGNIFICANCE GENE VARIANT ASSOCIATED WITH

NO VARIANTS OF KNOWN CLINICAL SIGNIFICANCE FOUND

Analysis & Interpretation

The data indicates that known harmful changes were not found among the genes that were tested. It is important to recognize the limitations of this test. No one's cancer risk is 0%. Each of us has a risk of developing various types of cancer. Specific risks factors for cancer depends on several factors, including your age, gender, family and medical histories, and lifestyle characteristics. This test did not look for changes in all genes associated with cancer (for a list of what is tested see the information below). There are genetic risk factors that cannot be identified using this test. Because of this, it is important to remember that a normal or negative result does not mean the patient should avoid being tested in other ways.

Genetic testing is only one way of looking for cancer risk. Another very important approach is to talk with the patient about various screening tests for specific cancers, like a mammogram for breast cancer, or a colonoscopy for colon cancer. Another important consideration is to look for "red flags" in the patient's family history. Red flags include a history of family members with rare cancers, cancers that develop before older age (before age 50), multiple separate types of cancer in the same family member, and multiple individuals on the same side of the family with the same type of cancer. If the family has any of these red flags, you may suggest a visit with a genetic counselor. Genetic counselors are experts in piecing together the details of family history and red flags into a plan for further testing and monitoring appropriate for the patient.

Speak with your patient about this genetic test, screening testing and detailing their family and medical histories. Additionally, you and your patient can view an informational video on what it means to have no variants that increase cancer risks.

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Patient Name	Patient ID No.	Patient Phone	Date of Birth	Age	Sex
TEST PATIENT	569665578		10/14/2002	14	F

Physician	Date/Time Collected	Date/Time Received	Date/Time
TEST PHYSICIAN			

Comment

TEST NAME	WITHIN RANGE	OUTSIDE RANGE	REFERENCE RANGE	UNITS
Methodology & Limitations				

The Cancer Screening Panel uses state-of-the-art sequencing technology to provide high quality results. Genomic DNA is extracted from dry buccal swabs using magnetic particle processing. DNA from patient samples are amplified with primers specific for the targeted regions using Oligo Directed Patch PCR (Varley, et. al.). Positive and negative controls are used with each run. Barcoded patient samples and positive controls are paired-end sequenced using Illumina NextGen sequencing technology. Targeted sequencing is performed on the entire coding region and intronic/exonic boundaries unless otherwise noted below. Sequences are aligned to the human reference genome and variants (Small Nucleotide Variations, Insertions and Deletions) are called. Large indels (>50 bp), rearrangements, rare abnormalities and structural variations may not be detected. Rare diagnostic errors may occur if variations occur in primer site locations.

The regions sequenced include many, but not all, genes that have been shown to affect our risk of developing cancer and/or impact medical management. The following genes are sequenced: APC, ATM, BARD1, BMPR1A, BRCA1, BRCA2, BRIP1, CDH1, CDKN2A, CHEK2, EPCAM, FH, FLCN, MLH1, MRE11, MSH2, MSH6, MUTYH, NBN, PALB2, PMS2, PTEN, RAD50, RAD51C, RAD51D, RINT1, SDHB, SMAD4, STK11, TP53, VHL, and XRCC2. Exon 30 of ATM, exon 1 of EPCAM, exons 11 and 14 of FCLN, exon 1 of PALB and exon 1 of RINT1, as well as some highly repetitive or low complexity regions, have also been excluded from analysis. Over 97% of the coding regions of these genes are covered by this panel. For a detailed list of gene transcripts and the reportable range, please visit www.kailosgenetics.com/panel/csp-2.3.1.

Extensive computational analysis is performed to validate the variants and reduce the likelihood of error. Qualified variants are compared to the NIH ClinVar database. Variants are reported as being Pathogenic or Likely Pathogenic if there is (a) sufficient support in ClinVar or (b) Kailos determines that a mutation would likely cause a deleterious frameshift or premature stop. 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 this report reflects the current state of knowledge at the time of reporting. The pathogenic classification of variants may change as new scientific information is learned. All data is reviewed for release by our Medical Director and/or our CLIA Lab Manager.

All pathogenic or likely pathogenic variants within the targeted regions are reported. We do not report benign and likely benign variants, as these variants most likely do not cause an increased cancer risk. Variants of uncertain significance (VUS) are also not reported as they would not be used to change medical management.