Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT W
WX0000003827 M 07/08/1978 45 Y

Referral Testing

Collected: 08/25/2023 15:49 Received: 08/25/2023 15:49

Test Name	Result	Flag	Ref-Ranges	Units	Site
BRCA PANEL					
Result	NEGATIVE				QCRL

NO CLINICALLY SIGNIFICANT VARIANTS IDENTIFIED
Test Performed at:
Quest Diagnostics Nichols Institute
33608 Ortega Highway
San Juan Capistrano, CA 92675-2042 I Maramica MD, PhD, MBA

VARIANT 1					
Gene	.				QCRL
Variant	.				QCRL
Classification	.				QCRL
VARIANT 2					
Gene 2	.				QCRL
Variant 2	.				QCRL
Classification 2	.				QCRL
VARIANT 3					
Gene 3	.				QCRL
Variant 3	.				QCRL
Classification 3	.				QCRL
VARIANT 4					
Gene 4	.				QCRL
Variant 4	.				QCRL
Classification 4	.				QCRL
VARIANT 5					
Gene 5	.				QCRL
Variant 5	.				QCRL
Classification 5	.				QCRL
VUS					
VUS(s)	.				QCRL
Gene List	.				QCRL

LAB: L - LOW, H - HIGH, AB - ABNORMAL, C - CRITICAL, . - NOT TESTED

F225000037
WX0000003827
Printed D&T: 08/28/23 08:54

Ordered By: KAJAL SITWALA, MD, PhD
WX00000000002365

Kajal V. Sitwala, MD, PhD - Medical Director
Form: MM RL1

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CLINICAL INTERPRETATION

Clinical Interpretation — NEGATIVE — QCRL

Comprehensive sequence analysis of the coding regions and flanking sequence of the gene(s) tested (see Methods and Limitations section) was negative for clinically significant variants. Inherent to the assay methodology, not all gross gene rearrangements or variants affecting gene expression or RNA splicing will be detected. This negative result does not rule out clinically significant variants in other genes associated with hereditary susceptibility to cancer, nor does it address risk for other hereditary conditions. Residual risk after this negative test result is influenced by the indication for testing. Cancer screening and prevention efforts should be guided by personal and family history. In some circumstances, additional genetic testing may be appropriate in addition to new testing options relevant for this individual as they become available in the future.

Genetic counseling is recommended for any individual undergoing genetic testing.

If this individual has one or more relatives who tested positive for a pathogenic or likely pathogenic variant in any of the tested genes, it is strongly recommended that the genetic test report from at least one such relative be provided to Quest Diagnostics.

Variant Interpretation — . — QCRL

COMMENTS

Reviewer — SEE NOTE — QCRL

Laboratory testing supervised and results monitored by

Resources — SEE NOTE — QCRL

Visit QuestHereditaryCancer.com for physician information, patient materials, FAQs, and testing resources. Call 1-866-GENE-INFO (1-866-436-3463) for genetic counseling consultations, pre-authorization services, and help finding patient genetic counseling services.

Methods and Limitations — SEE NOTE — QCRL

Methods: In this assay, enzymatically sheared DNA fragments representing the entire coding region and the splice junction sites of

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the interrogated genes are selectively enriched through exon capture using DNA baits, and then subjected to nucleotide sequence analysis on a massively parallel sequencing platform. Both genes, BRCA1 and BRCA2, are examined for single nucleotide variants (SNVs), insertions and deletions (InDels), and copy number variants (CNVs) involving deletions and/or duplications of one or more exons, including those that affect the entire genes. CNVs are assessed by bioinformatic analysis of sequencing reads and, when indicated, confirmed by an orthogonal method.

The following NCBI reference transcript sequences were utilized for analysis: BRCA1 (NM 007294.3), BRCA2 (NM 000059.3). Reference genome: hg19 (build37).

Limitations: This assay cannot detect variants affecting unexamined gene regions (e.g. deep intronic), nor variants in other unlisted genes. In addition, the effect of rare or novel variants on mRNA splicing, protein synthesis, and/or protein function may remain unclear. Variants due to mosaicism, somatic variants from pre-malignant or malignant cells, false positive, or false negative results may rarely occur. While this assay detects copy number variants (CNVs) spanning a region of interest (ROI) 100bp or more in size with a high level of sensitivity, CNV detection in smaller ROIs, which are clinically rare, is reduced. Results should be interpreted in the context of clinical findings, relevant history, and other laboratory data. This assay does not analyze all genes associated with hereditary cancer. In some situations, additional genetic testing may be appropriate.

Additional Information	SEE NOTE				QCRL

Benign and likely benign variants with no known clinical significance are reported only by request. If a variant is reclassified with clinical implications, Quest Diagnostics will endeavor to contact the ordering provider.

Providers may contact Quest Genomics Client Services at 1-866-GENEINFO (1-866-436-3463) for assistance with result interpretation, questions about variant classification, or to discuss additional testing.

The classification and interpretation of the variant(s) identified reflect the current state of Quest Diagnostics' understanding at the time of this report. Variant classification and interpretation are subject to professional judgment, and may change for a variety of reasons, including but not limited to, updates in classification guidelines and availability of additional scientific and clinical information. This test result should be used in conjunction with the health care provider's clinical evaluation. Inquiry regarding

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potential changes to the classification of the variant is strongly recommended prior to making any future clinical decision. For questions regarding variant classification updates, please call Quest Diagnostics at 866-GENEINFO (436-3463) to speak to a genetic counselor or laboratory director, or visit http://questdiagnostics.com/variantiq.

For patients who are interested in sharing de-identified genetic and health information to improve understanding of genetics and health, please visit https://GenomeConnect.org. GenomeConnect is a third party online registry designed by the Clinical Genome Resource (ClinGen) and is not affiliated with Quest Diagnostics in any way.

This test was developed and its analytical performance characteristics have been determined by Quest Diagnostics Nichols Institute San Juan Capistrano. It has not been cleared or approved by FDA. This assay has been validated pursuant to the CLIA regulations and is used for clinical purposes.

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San Juan Capistrano, CA 92675-2042 I Maramica MD, PhD, MBA

Performing Site:
QCRL: QUEST DIAGNOSTICS REFERENCE LAB CAPISTRANO 33608 Ortega Highway San Juan Capistrano CA 92675

Reported Date: 2023.08.28 15:52 BRCAP