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Comprehensive BRACAnalysis® BRCA1 and BRCA2 Analysis Result



PHYSICIAN	SPECIMEN	PATIENT

Test Results and Interpretation

NO MUTATION DETECTED

It is our understanding that this patient was identified for testing due to a personal or family history suggestive of hereditary breast and ovarian cancer. Analysis consists of sequencing of all translated exons and immediately adjacent intronic regions of the BRCA1 and BRCA2 genes and a test for five specific BRCA1 rearrangements. There are additional large genomic rearrangements in BRCA1 and in BRCA2, which are not detected by this test, but can be identified with the BRACAnalysis Rearrangement Test (BART). The classification and interpretation of all variants identified in this assay reflects the current state of scientific understanding at the time this report was issued. In some instances, the classification and interpretation of such variants may change as new scientific information becomes available.

No deleterious mutation was found in BRCA1 or BRCA2 in this individual. This test is designed to identify mutations in 22 exons and approximately 750 adjacent intronic base pairs of BRCA1 as well as 26 exons and approximately 950 adjacent intronic base pairs of BRCA2 (a total of over 17,600 base pairs analyzed). This test is also designed to detect five specific BRCA1 genomic rearrangements, including a 3.835-kb deletion involving exon 13, a 510-bp deletion involving exon 22, a 6-kb insertion involving exon 13, a 7.1-kb deletion involving exons 8 and 9, and a 26-kb deletion involving exons 14-20 (see Technical Specifications for references). The proportion of all BRCA1 genomic rearrangements represented by these specific abnormalities has not yet been characterized. There are other, uncommon genetic abnormalities in BRCA1 and BRCA2 that this test will not detect. This result, however, rules out the majority of abnormalities believed to be responsible for hereditary susceptibility to breast and ovarian cancer (Ford D et al., Am J Human Genetics 62:676-689, 1998). If this individual has never had breast or ovarian cancer, it is recommended that testing an affected relative be considered to help clarify the clinical significance of this individual's negative test result. If this patient has a relative with a known mutation in BRCA1 or BRCA2, it is important to confirm that this family mutation is detected with the BRACAnalysis Rearrangement Test (BART).

Please contact Myriad Professional Support at 1-800-469-7423 to discuss any questions regarding this result.

These test results should only be used in conjunction with the patient's clinical history and any previous analysis of appropriate family members. It is strongly recommended that these results be communicated to the patient in a setting that includes appropriate counseling. The accompanying Technical Specifications summary describes the analysis, method, performance characteristics, nomenclature, and interpretive criteria of this test. This test was developed and its performance characteristics determined by Myriad Genetic Laboratories. It has not been cleared or approved by the U.S. Food and Drug Administration. FDA has determined that clearance or approval for laboratory-developed tests is not necessary.