



BRCAAnalysis CDx®
FDA Approved BRCA1 and BRCA2 Analysis Result

PHYSICIAN
Test Physician, MD
123 Any Street
Anytown, UT 11111

SPECIMEN
 Specimen Type: **Blood**
 Draw Date: **Dec 15, 2014**
 Accession Date: **Dec 15, 2014**
 Report Date: **Jan 20, 2016**

PATIENT
 Name: **Patient, Test**
 Date of Birth: **Jan 01, 2000**
 Patient ID:
 Gender: **Female**
 Accession #: **01888530-BLD**
 Requisition #: **4345344**

Test Results and Interpretation

NO MUTATION DETECTED

<u>Test Performed</u>	<u>Result</u>	<u>Interpretation</u>
<i>BRCA1</i> sequencing	No Mutation Detected	No Mutation Detected
comprehensive rearrangement	No Mutation Detected	No Mutation Detected
<i>BRCA2</i> sequencing	No Mutation Detected	No Mutation Detected
comprehensive rearrangement	No Mutation Detected	No Mutation Detected

The majority of deleterious or suspected deleterious variants identified by Myriad in *BRCA1* and *BRCA2* are classified using objective criteria based on the type and genomic position of the variants. Deleterious or suspected deleterious mutations classified by other criteria that are based on available evidence may be subject to change. If you have questions or concerns about how the variant(s) in this result report was classified, please contact Myriad.

Intended Use: BRCAAnalysis CDx® is an *in vitro* diagnostic device intended for the qualitative detection and classification of variants in the protein coding regions and intron/exon boundaries of the *BRCA1* and *BRCA2* genes using genomic DNA obtained from whole blood specimens collected in EDTA. Single nucleotide variants and small insertions and deletions (indels) are identified by polymerase chain reaction (PCR) and Sanger sequencing. Large deletions and duplications in *BRCA1* and *BRCA2* are detected using multiplex PCR. Results of the test are used as an aid in identifying ovarian cancer patients with deleterious or suspected deleterious germline *BRCA* variants, who are or may become eligible for treatment with Lynparza™ (olaparib). This assay is for professional use only and is to be performed only at Myriad Genetic Laboratories, a single laboratory site located at 320 Wakara Way, Salt Lake City, UT 84108.

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Please contact Myriad at 1-800-469-7423 with any questions or feedback regarding services provided.

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 Laboratory Director

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 Chief Medical Officer

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 test results be communicated to the patient in a setting that includes appropriate counseling. Lynparza is a trademark of the AstraZeneca group of companies.

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The information below has not been reviewed and approved by the FDA.

This assay may identify ovarian cancer patients with a deleterious or suspected deleterious *BRCA1* or *BRCA2* mutation who may benefit from treatment with Lynparza™ (olaparib). Full prescription information for Lynparza™ (olaparib) is available at http://www.azpicentral.com/Lynparza/pi_lynparza.pdf. In addition, the assay may identify patients at risk for Hereditary Breast and Ovarian Cancer (HBOC) associated with *BRCA1* and *BRCA2* deleterious or suspected deleterious mutations.

No deleterious mutation was found in *BRCA1* or *BRCA2* in this individual by sequencing and quantitative PCR analysis. 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 duplications and deletions involving the promoter region and coding exons of *BRCA1* and *BRCA2*. There are other, rare 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).