



55300689

CONFIDENTIAL

BRACAnalysis CDx® Genetic Test Result

FDA Approved *BRCA1* and *BRCA2* Analysis Result

BRACAnalysis CDx®

Germline Companion Diagnostic Test

RECEIVING HEALTHCARE PROVIDER

Test HCP, MD
 Test Medical Center
 6609 BLANCO RD STE 200
 SAN ANTONIO, TX 78216

SPECIMEN

Specimen Type: Blood
 Draw Date: Apr 20, 2023
 Accession Date: Apr 20, 2023
 Report Date: Apr 20, 2023

PATIENT

Legal Name: Pt Last Name,
 Pt First Name
 Date of Birth: Apr 20, 1978
 Patient ID: Patient id
 Sex at Birth: F
 Accession #: 07007713-BLD
 Requisition #: 47073850



GENETIC RESULT: NEGATIVE - NO CLINICALLY SIGNIFICANT MUTATION IDENTIFIED

Note: "CLINICALLY SIGNIFICANT," as defined in this report, is a genetic change that is associated with the potential to alter medical intervention.

ADDITIONAL FINDINGS: NO VARIANT(S) OF UNCERTAIN SIGNIFICANCE (VUS) IDENTIFIED

ADDITIONAL INFORMATION

Genes Analyzed: Unless otherwise noted sequencing and large rearrangement analyses were performed on the following genes:

BRCA1, *BRCA2*

Intended Use: BRACAnalysis 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 patients who are or may become eligible for treatment with the targeted therapies listed in Table 1 in accordance with the most recently approved therapeutic product labeling.

Table 1. Companion Diagnostic Indications

Tumor Type	Biomarker	Therapy
Breast Cancer	Deleterious or suspected deleterious mutations in <i>BRCA1</i> and <i>BRCA2</i> genes	Lynparza® (olaparib)
		Talzenna® (talazoparib)
Ovarian Cancer	Deleterious or suspected deleterious mutations in <i>BRCA1</i> and <i>BRCA2</i> genes	Lynparza® (olaparib)
		Zejula® (niraparib)
Pancreatic Cancer	Deleterious or suspected deleterious mutations in <i>BRCA1</i> and <i>BRCA2</i> genes	Lynparza® (olaparib)
Prostate Cancer	Deleterious or suspected deleterious mutations in <i>BRCA1</i> and <i>BRCA2</i> genes	Lynparza® (olaparib)



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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.

Contraindication:

- Patients who have undergone a previous allogeneic bone marrow transplant should not be tested with the BRACAnalysis CDx[®] test.

Limitations:

- Patients under consideration for testing who have been diagnosed with a hematologic malignancy, such as leukemia, could generate a positive (deleterious or suspected deleterious) result that is somatic, and not germline, due to chromosome instability.
- The classification and interpretation of all variants identified reflects the current state of scientific understanding at the time the result report is issued. In some instances, the classification and interpretation of variants may change as scientific information becomes available.
- Limitation: In Ovarian Cancer, ~70% of tumor *BRCA1* or *BRCA2* mutation positive patients are estimated to have a germline mutation while ~30% of patients are estimated to have a somatic mutation. In Prostate Cancer, ~50% of tumor *BRCA1* or *BRCA2* mutation positive patients are estimated to have a germline mutation while ~50% of patients are estimated to have a somatic mutation. The BRACAnalysis CDx test detects germline mutations only, not somatic mutations from patient's blood sample. A negative result using the BRACAnalysis CDx blood test in ovarian and prostate cancer patients does not rule out the possibility of a somatic *BRCA1* or *BRCA2* mutation in tumor tissue from these patients.

For more detailed information, including a complete list of Contraindications, Limitations, Warnings and Precautions of the assay, please see page 2 of the BRACAnalysis CDx[®] Technical Information at: <https://s3.amazonaws.com/myriad-web/BRACAnalysisCDxTS.pdf>

The majority of deleterious or suspected deleterious mutations identified by Myriad in *BRCA1* and *BRCA2* are classified using objective criteria based on the type and genomic position of the mutations. Other deleterious or suspected deleterious mutations may be classified by other criteria that are based on available evidence. Myriad's myVision[®] Variant Classification Program performs ongoing evaluations of variant classifications. In certain cases, the healthcare provider may be contacted for more clinical information or to arrange family testing to aid in variant classification. When new evidence about a variant is identified and determined to result in clinical significance and management changes, that information will automatically be made available to the healthcare provider through an amended report. If you have any questions or concerns about how the variant(s) in this result were classified, please contact Myriad.

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

This Authorized Signature
pertains to this laboratory report:

Benjamin B. Roa, PhD
Diplomate ABMG
Laboratory Director

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. This test was developed and its performance characteristics determined by Myriad Genetic Laboratories. Myriad is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) as qualified to perform high complexity clinical laboratory testing.



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The following information has not been reviewed and approved by the FDA. This assay identifies patients at risk for Hereditary Breast and Ovarian Cancer (HBOC) syndrome associated with deleterious or suspected deleterious BRCA1 or BRCA2 variants. Additional information is provided for hereditary cancer management purposes.

ADDITIONAL TREATMENT INFORMATION

This assay is intended to be used as an aid in treatment decision making for the PARP inhibitors Lynparza[®] (olaparib), Zejula[®] (niraparib) and Talzenna[®] (talazoparib). Full prescription information for Lynparza[®] (olaparib) is available at: http://www.azpicentral.com/Lynparza/pi_lynparza.pdf. Full prescription information for Zejula[®] (niraparib) is available at: https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Zejula_Capsules/pdf/ZEJULA-CAPSULES-PI-PIL.PDF. Full prescription information for Talzenna[®] (talazoparib) is available at: <http://labeling.pfizer.com/ShowLabeling.aspx?id=11046>. For more detailed information including Performance Characteristics, please find the complete Technical Information at: <https://myriad.com/technical-specifications>.

ASSOCIATED CANCER RISKS AND CLINICAL MANAGEMENT

If a clinically significant mutation is identified, please see the management tool associated with this report for a summary of cancer risk and professional society medical management guidelines that may be useful in developing a plan for this patient. Testing of other family members may assist in the interpretation of this patient's test result.

DETAILS ABOUT NON-CLINICALLY SIGNIFICANT VARIANTS

All individuals carry DNA changes (i.e., variants), and most variants do not increase an individual's risk of cancer or other diseases. When identified, variants of uncertain significance (VUS) are reported. Likely benign variants (Favor Polymorphisms) and benign variants (Polymorphisms) are not reported and available data indicate that these variants most likely do not cause increased cancer risk. Present evidence does not suggest that non-clinically significant variant findings be used to modify patient medical management beyond what is indicated by the personal and family history and any other clinically significant findings.



Myriad Genetics Laboratories, Inc.
320 Wakara Way
Salt Lake City, Utah 84108
PH: +1 (877) 283-6709
FX: +1 (801) 883-8998
www.myriad.com

Outside U.S.A

Email: CustomerSupport@myriadgenetics.eu



Myriad International GmbH
Nattermannallee 1
50829 Cologne, Germany



The Myriad Genetics BRACAnalysis CDx[®] test was developed and performance characteristics were determined by Myriad Genetic Laboratories, Inc. and in compliance to In-Vitro Diagnostic Device Directive (98/79/EC) and is CE marked. Myriad is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) as qualified to perform high complexity clinical laboratory testing. Myriad is compliant with multiple international standards including, ISO13485:2016 and ISO 15189: 2012 as applicable.

Sex assigned at birth refers to the classification of an individual as male or female, often based on physical characteristics at birth.