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: | Nov 11, 2024 |
| Accession Date: | Nov 11, 2024 |
| Report Date: | Nov 12, 2024 |

**PATIENT**

| | |
|---|---|
| Legal Name: | Pt Last Name, Pt First Name |
| Date of Birth: | Nov 11, 1979 |
| Patient ID: | Patient id |
| Sex at Birth: | F |
| Accession #: | 07383013-BLD |
| Requisition #: | 47822949 |

## GENETIC RESULT: POSITIVE - CLINICALLY SIGNIFICANT MUTATION IDENTIFIED

| GENE | MUTATION | INTERPRETATION |
|---|---|---|
| *BRCA1* | c.68_69del (p.Glu23Valfs*17)<br>Heterozygous | DELETERIOUS |

## 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 *BRCA1* and *BRCA2* genes | Lynparza® (olaparib) |
| | | Talzenna® (talazoparib) |
| Ovarian Cancer | Deleterious or suspected deleterious mutations in *BRCA1* and *BRCA2* genes | Lynparza® (olaparib) |
| | | Zejula® (niraparib) |
| Pancreatic Cancer | Deleterious or suspected deleterious mutations in *BRCA1* and *BRCA2* genes | Lynparza® (olaparib) |
| Prostate Cancer | Deleterious or suspected deleterious mutations in *BRCA1* and *BRCA2* genes | Lynparza® (olaparib) |

Myriad genetics

# BRACAnalysis CDx® Genetic Test Result

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The BRACAnalysis CDx® assay is for professional use only and is performed exclusively at Myriad Genetic Laboratories, Inc. site located in Salt Lake City, UT.

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.**

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.

This **Authorized Signature** pertains to this laboratory report:

**Benjamin B. Roa, PhD**
Diplomate ABMGG
Laboratory Director

Genetic testing was completed by CLIA and CAP accredited laboratories in the United States located at: 322 N 2200 W, Salt Lake City, UT 84116 CLIA IDs: 46D2275645
The following personnel codes and laboratory director signature may reflect remote review of digital data: 4109, 4745

# BRACAnalysis CDx® Genetic Test Result

Name: **Pt Last Name, Pt First Name** DOB: **Nov 11, 1979** Accession #: **07383013-BLD** Report Date: **Nov 12, 2024**

***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.***

## DETAILS ABOUT: *BRCA1* c.68_69del (p.Glu23Valfs*17): NM_007294.3; (aka: 185delAG, 187delAG)

**Functional Significance: Deleterious - Abnormal Protein Production and/or Function**

The heterozygous germline *BRCA1* mutation c.68_69del is predicted to result in the premature truncation of the *BRCA1* protein at amino acid position 39 (p.Glu23Valfs*17).

**Clinical Significance: High Risk**

If this individual is of Ashkenazi Jewish ancestry, it is recommended that follow-up testing of relatives of this individual include analysis for the mutations c.68_69del (p.Glu23Valfs*17) and c.5266dupC (p.Gln1756Profs*74) in *BRCA1* and c.5946del (p.Ser1982Argfs*22) in *BRCA2* because of reports of coexistence of two high-frequency germline mutations in some Ashkenazi families (Ramus SJ et al. Nature Genetics 1997. 15:14-15). This mutation is associated with increased cancer risk and should be regarded as clinically significant.

## 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.

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Email: CustomerSupport@myriadgenetics.eu

EC REP
QbD RepS BV
Groenenborgerlaan 16
2610 Wilrijk, Belgium

CE IVD

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.

Management Tool - BRACAnalysis CDx®

# *BRCA1* and *BRCA2* Analysis

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| Requisition #: | 47822949 |

## GENETIC RESULT: POSITIVE - CLINICALLY SIGNIFICANT MUTATION IDENTIFIED

| GENE | MUTATION | THIS GENETIC TEST RESULT IS ASSOCIATED WITH THE FOLLOWING CANCER RISKS: |
|---|---|---|
| *BRCA1* | **c.68_69del (p.Glu23Valfs*17)**<br>Heterozygous | HIGH RISK: Breast, Ovarian<br>ELEVATED RISK: Pancreatic |

Please see the Genetic Test Result for more details on any variant(s) detected in this patient, including variant classification information.

The terms "male", "female", "he", "she", "women", and "men" refer to sex assigned at birth.

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

## CLINICAL OVERVIEW OF GENETIC FINDINGS

### *BRCA1*-associated hereditary breast and ovarian cancer syndrome

- This patient has been found to have a mutation in the *BRCA1* gene. Individuals with mutations in *BRCA1* have *BRCA1*-associated hereditary breast and ovarian cancer syndrome.
- Women with *BRCA1* mutations have a risk for breast cancer that is greatly increased over the 12.5% lifetime risk for women in the general population of the United States. Most breast cancers in women with *BRCA1* mutations are Triple Negative Breast Cancer (TNBC), a type of breast cancer lacking estrogen and progesterone receptors, and not expressing Her2.
- Women with *BRCA1* mutations also have high risks for ovarian, fallopian tube, and primary peritoneal cancer.
- Men with *BRCA1* mutations have an elevated risk for breast and prostate cancer. The increased risk for prostate cancer may be most significant at younger ages. Additionally, men with a *BRCA1* mutation have a higher risk for an aggressive prostate cancer.
- Male and female patients with *BRCA1* mutations have an elevated risk for exocrine pancreatic cancer. These are cancers developing in the enzyme-secreting cells of the pancreas.
- Based on limited data of a slightly increased risk of serous uterine cancer in individuals with *BRCA1* mutations, the risks and benefits of concurrent hysterectomy at the time of risk-reducing salpingo-oophorectomy should be discussed. Individuals who undergo hysterectomy are candidates for hormone replacement therapy (HRT) with estrogen alone, which is associated with a lower risk of breast cancer than HRT with estrogen and progesterone.
- Although there are high cancer risks for patients with *BRCA1* mutations, there are interventions that have been shown to be effective at reducing many of these risks. Guidelines from the National Comprehensive Cancer Network (NCCN) for the medical management of patients with *BRCA1* mutations are listed below. It is recommended that patients with *BRCA1* mutations be managed by a multidisciplinary team with experience in the prevention and treatment of the cancers associated with *BRCA1* mutations.

# Management Tool - BRACAnalysis CDx®

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## WHAT ARE THE PATIENT'S CANCER RISKS?

The risk table or tables that follow show the clinically significant cancer risks identified as part of this patient's testing. The risk for each gene result is provided separately. If the risk for any individual cancer is affected by more than one of these results, the risk associated with each finding is listed in a separate table. At this time, there is not enough information to estimate risks for cancers affected by more than one gene mutation, or risks based on both gene mutations and personal/family history.

The cancer risks in the table(s) below are estimates based on the best data currently available in the published literature. Risks for individual patients may be significantly higher or lower depending on personal and family history and the presence or absence of other risk factors.

### Risks Due to *BRCA1*-associated hereditary breast and ovarian cancer syndrome

| CANCER TYPE | CANCER RISK | RISK FOR GENERAL POPULATION | RELATED TO |
|---|---|---|---|
| FEMALE BREAST | | | |
| To age 50 | 28%-51%, with a particularly increased risk for triple negative breast cancer (TNBC). | 2.1% | *BRCA1* |
| To age 70 | 46%-87%, with a particularly increased risk for triple negative breast cancer (TNBC). | 7.5% | *BRCA1* |
| Second primary within 5 years of first breast cancer diagnosis | 9%-13% | 1.6% | *BRCA1* |
| OVARIAN | | | |
| To age 50 | 8%-23% | 0.2% | *BRCA1* |
| To age 70 | 39%-63% | 0.6% | *BRCA1* |
| Ovarian cancer within 10 years of a breast cancer diagnosis | 12.7% | <1.0% | *BRCA1* |
| PANCREATIC | | | |
| To age 80 | Elevated risk | 1.1% | *BRCA1* |

## WHAT MANAGEMENT FOR CANCER RISKS SHOULD BE CONSIDERED?

This overview of clinical management guidelines is based on the patient's genetic test results. Medical management guidelines are summarized from established medical societies, primarily the National Comprehensive Cancer Network (NCCN). If there are overlapping management guidelines for any individual cancer due to more than one gene result, the guidelines associated with each finding are listed in separate tables, even if they are the same. At this time, there are no medical society guidelines for how to adjust management when there are multiple sources of risk, such as from more than one gene mutation. In these cases, it may be appropriate to use the most aggressive management option provided.

The overview provided below should not be used as the sole source of information to determine medical management. The references cited should always be consulted for more details and updates to the recommendations.

No information is provided related to treatment of a previous or existing cancer or polyps. The recommendation summaries below may require modification due to the patient's personal medical history, past surgeries and other treatments. Patients with a past history of cancer, benign tumors, or pre-cancerous findings may be candidates for long term surveillance and risk-reduction strategies beyond what is necessary for the treatment of their initial diagnosis. Any discussion of medical management options is for general information purposes only and does not constitute a recommendation. While genetic testing and medical society recommendations provide important and useful information, medical management decisions should be made in consultation between each patient and their healthcare provider.

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Name: **Pt Last Name, Pt First Name** DOB: **Nov 11, 1979** Accession #: **07383013-BLD** Report Date: **Nov 12, 2024**

## Management Options for *BRCA1*-associated hereditary breast and ovarian cancer syndrome

| PROCEDURE | AGE TO BEGIN | FREQUENCY Unless otherwise indicated by findings | RELATED TO |
|---|---|---|---|
| **FEMALE BREAST** | | | |
| Breast awareness - Women should be familiar with their breasts and promptly report changes to their healthcare provider. Periodic, consistent breast self-examination (BSE) may facilitate breast awareness. [2] | 18 years | NA | *BRCA1* |
| Clinical breast examination [2] | 25 years | Every 6 to 12 months | *BRCA1* |
| Breast MRI with contrast [2] | 25 years, or individualized to a younger age if a relative has been diagnosed younger than age 30. | Annually | *BRCA1* |
| Mammography [2] | 30 years. If MRI unavailable, start at 25 years, or individualized to a younger age if a relative has been diagnosed younger than age 30. | Annually | *BRCA1* |
| Consider risk-reducing mastectomy. [2] | Individualized | NA | *BRCA1* |
| Consider options for breast cancer risk-reduction agents (i.e. tamoxifen). [2] | Individualized | NA | *BRCA1* |
| **OVARIAN** | | | |
| Bilateral salpingo-oophorectomy (BSO). Discuss the risks and benefits of concurrent hysterectomy at the time of BSO. [2] | 35 to 40 years, upon completion of childbearing | NA | *BRCA1* |
| Consider options for ovarian cancer risk-reduction agents (i.e. oral contraceptives). [2,5] | Individualized | NA | *BRCA1* |
| **PANCREATIC** | | | |
| For patients with a family history of pancreatic cancer, consider available options for pancreatic cancer screening, including the possibility of endoscopic ultrasonography (EUS) and MRI/magnetic resonance cholangiopancreatography (MRCP). It is recommended that patients who are candidates for pancreatic cancer screening be managed by a multidisciplinary team with experience in screening for pancreatic cancer, preferably within research protocols. [3] | Age 50, or 10 years younger than the earliest age of pancreatic cancer diagnosis in the family | Annually | *BRCA1* |
| Provide education about ways to reduce pancreatic cancer risk, such as not smoking and losing weight. [8] | Individualized | Individualized | *BRCA1* |
| **FOR PATIENTS WITH A CANCER DIAGNOSIS** | | | |
| For patients with a gene mutation and a diagnosis of cancer, targeted therapies may be available as a treatment option for certain tumor types (e.g., platinum chemotherapy, PARP-inhibitors) [1,4,6,7,8,9,10] | NA | NA | *BRCA1* |

1. Armstrong DK, et al. NCCN Clinical Practice Guidelines in Oncology®: Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer. V 1.2023. Dec 22. Available at https://www.nccn.org.
2. Daly M et al. NCCN Clinical Practice Guidelines in Oncology®: Genetic/Familial High-Risk Assessment: Breast, Ovarian and Pancreatic. V 3.2023. Feb 13. Available at https://www.nccn.org.
3. Goggins M, et al. Management of patients with increased risk for familial pancreatic cancer: updated recommendations from the International Cancer of the Pancreas Screening (CAPS) Consortium. Gut. 2020 69:7-17. PMID: 31672839.
4. Gradishar WJ et al. NCCN Clinical Practice Guidelines in Oncology®: Breast Cancer. V 4.2023. Mar 23. Available at https://www.nccn.org.
5. Gupta S, et al. NCCN Clinical Practice Guidelines in Oncology® Genetic/Familial High-Risk Assessment: Colorectal. V 1.2023. May 30. Available at https://www.nccn.org.
6. Schaeffer E, et al. NCCN Clinical Practice Guidelines in Oncology®: Prostate Cancer. V 1.2023. Sep 16. Available at https://www.nccn.org.
7. Tempero MA, et al. NCCN Clinical Practice Guidelines in Oncology®: Ampullary Adenocarcinoma. V 2.2022. Dec 6. Available at https://www.nccn.org.
8. Tempero MA, et al. NCCN Clinical Practice Guidelines in Oncology®: Pancreatic Adenocarcinoma. V 2.2022. Dec 6. Available at https://www.nccn.org.
9. https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/209115s000lbl.pdf
10. https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/208558s002lbl.pdf

**Notes for Personalized Management:**

## INFORMATION ON HOW CANCER RISKS AND MANAGEMENT ARE DETERMINED

The Management Tool provides cancer risk levels and management recommendations based on analysis of the genetic results (see Genetic Result). Additional details and references for cancer risks and management recommendations can be found on myriadmyrisk.com/gene-table/.

- A comprehensive risk assessment may include other aspects of the patient's personal/family medical history, as well as lifestyle, environment and other factors.
- No management recommendations are provided related to treatment of a previous or existing cancer or polyps. The recommendations provided may require modification based on the patient's personal medical history, surgeries and other treatments. Patients with a personal history of cancer, benign tumors or pre-cancerous findings may be candidates for long term surveillance and risk-reduction strategies beyond what is necessary for the treatment of their initial diagnosis.
- Patients who have a clinical diagnosis of a genetic cancer syndrome (e.g., Lynch syndrome) may have different management recommendations than provided. Management should be personalized based on all known clinical diagnoses.
- The Genetic Test Result Summary includes: female breast, male breast, colorectal, endometrial, gastric, ovarian, pancreatic and prostate cancers, and melanoma. In this summary a gene associated cancer risk is described as "High Risk" for a cancer type if all of the following conditions are met: the absolute risk of cancer is approximately 5% or higher, the increase in risk over the general population is approximately 2 to 3-fold or higher, and there is significant data from multiple studies supporting the cancer risk estimate. A gene is described as "Elevated Risk" for a cancer type if there is sufficient data to support an increase in cancer risk over the general population risk, but not all criteria for "High Risk" are met.

## INFORMATION FOR FAMILY MEMBERS

Family members should talk to their healthcare providers about hereditary cancer testing to help define their own risk and assist in the interpretation of this patient's genetic test result.

- This patient's relatives are at risk for carrying the same mutation(s) and associated cancer risks as this patient. Cancer risks for individuals who have this/these mutation(s) are provided below.

- **Family members should talk to a healthcare provider about genetic testing.** Close relatives such as parents, children, and siblings have the highest chance of having the same mutation(s) as this patient. Other more distant relatives such as cousins, parents siblings, and grandparents also have a chance for carrying the same mutation(s). Testing of at-risk relatives can identify those family members with the same mutation(s) who may benefit from surveillance and early intervention. More resources for family testing are available at MySupport360.com.

### Additional Information for *BRCA1*-associated hereditary breast and ovarian cancer syndrome

- In rare instances, an individual may inherit mutations in both copies of the *BRCA1* gene, leading to the condition Fanconi anemia, complementation group S (FANCS). This condition is rare and may include physical abnormalities, developmental delay, and a high risk for cancer. The children of this patient are at risk of inheriting FANCS only if the other parent is also a carrier of a *BRCA1* mutation. Screening the other biological parent of any children for *BRCA1* mutations may be appropriate.
- Parents who are concerned about the possibility of passing on a *BRCA1* mutation to a future child may want to discuss options for prenatal testing and assisted reproduction techniques, such as pre-implantation genetic diagnosis (PGD).

## CANCER RISK FOR *BRCA1* CLINICALLY SIGNIFICANT MUTATION

| CANCER TYPE | CANCER RISK | RISK FOR GENERAL POPULATION |
|---|---|---|
| | FEMALES | |
| FEMALE BREAST | | |
| To age 50 | 28%-51%, with a particularly increased risk for triple negative breast cancer (TNBC). | 2.1% |
| To age 70 | 46%-87%, with a particularly increased risk for triple negative breast cancer (TNBC). | 7.5% |
| Second primary within 5 years of first breast cancer diagnosis | 9%-13% | 1.6% |
| OVARIAN | | |
| To age 50 | 8%-23% | 0.2% |
| To age 70 | 39%-63% | 0.6% |
| Ovarian cancer within 10 years of a breast cancer diagnosis | 12.7% | <1.0% |
| | MALES | |
| PROSTATE | | |
| To age 70 | Up to 16% | 6.3% |
| MALE BREAST | | |
| To age 70 | 1.2% | 0.1% |
| | FEMALES AND MALES | |
| PANCREATIC | | |
| To age 80 | Elevated risk | 1.1% |

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END OF MANAGEMENT TOOL