

BRACAnalysis CDx[®]

Germline Companion Diagnostic Test



Provider guide

Confidently recommend an appropriate PARP inhibitor with fast and accurate *BRCA1/2* results

Myriad
genetics[®]

Confidently recommend an appropriate PARP inhibitor with fast and accurate *BRCA1/2* results

Germline *BRCA1/2* status is a critical biomarker to help you determine the appropriate therapy for your patients with breast, ovarian, pancreatic, or prostate cancer.

BRACAnalysis CDx[®] was designed and FDA-approved to quickly provide accurate germline *BRCA1/2* reports so you can confidently recommend an appropriate PARP inhibitor without delay.

BRACAnalysis CDx test includes:



Fast results

Turnaround time: less than two weeks



Accurate answers

FDA-approved with Medicare coverage



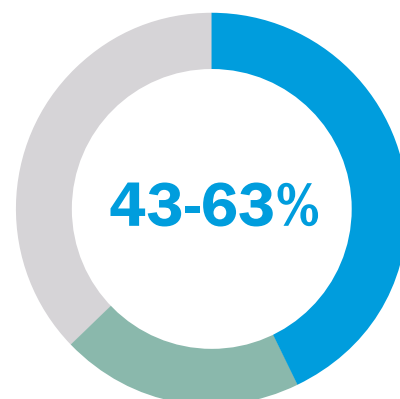
Better coverage

Industry leading and independently verified lab accuracy

The importance of variant classification

Myriad Genetic Laboratories has over 25 years of experience in variant classification and reclassification of *BRCA1/2*. The resulting analysis and interpretation of the variants reduces the VUS rate in genetic test results and provides confidence for oncologists when determining the appropriate therapy for their patients.

43-63% of gBRCA mutations identified as VUSs at competing labs can be definitively classified using Myriad Genetics' variant classification program¹







VUS = variant of uncertain significance

NCCN guidelines® recommend germline *BRCA1/2* testing for patients with breast, ovarian, pancreatic, and prostate cancer²

- No family history is needed for patients to meet genetic testing guidelines with these cancers
- Testing at diagnosis can help you determine an appropriate treatment plan for your patients



FDA-approved targeted therapies

Tumor type	Biomarker	Therapy
 Breast cancer	Deleterious or suspected deleterious mutations in <i>BRCA1</i> and <i>BRCA2</i> genes	<ul style="list-style-type: none">• Lynparza® (olaparib)• Talzenna® (talazoparib)
 Ovarian cancer	Deleterious or suspected deleterious mutations in <i>BRCA1</i> and <i>BRCA2</i> genes	<ul style="list-style-type: none">• Lynparza® (olaparib) - treatment / maintenance• Rubraca® (rucaparib)
 Pancreatic cancer	Deleterious or suspected deleterious mutations in <i>BRCA1</i> and <i>BRCA2</i> genes	<ul style="list-style-type: none">• Lynparza® (olaparib)
 Prostate cancer	Deleterious or suspected deleterious mutations in <i>BRCA1</i> and <i>BRCA2</i> genes	<ul style="list-style-type: none">• Lynparza® (olaparib)



One-week turnaround time option for patients with pancreatic cancer

Timing is critical to identify patients who are eligible for olaparib maintenance treatment following first-line platinum-based chemotherapy. BRACAnalysis CDx[®] has a priority option for patients with pancreatic cancer with a one-week turnaround time. This accelerated process requires a MyriadPro account and the use of the priority label for patients with pancreatic cancer.

[Visit BRACAnalysisCDx.com](https://BRACAnalysisCDx.com) to learn more about the ordering process

Cost should never be a barrier when your patients need genetic testing to determine their next treatment

That's why it's our promise to make it accessible and affordable.
Through insurance and financial assistance:

97%

Insurers have coverage for hereditary cancer testing

75%

Patients pay \$0 for testing at Myriad³

≥90%

Patients have or will qualify for a payment of \$100 or less³



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 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) -treatment/maintenance
		Rubraca [®] (rucaparib)
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)

Detection of deleterious or suspected deleterious germline *BRCA1* and *BRCA2* mutations by the BRACAnalysis CDx test in ovarian cancer patients is also associated with enhanced progression-free survival (PFS) from Zejula[®] (niraparib) or Rubraca[®] (rucaparib) maintenance therapy.

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.

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. The BRACAnalysis CDx test detects germline mutations only, not somatic mutations from a patient's blood samples. A negative result using the BRACAnalysis CDx blood test in ovarian cancer patients does not rule out the possibility of a somatic *BRCA1* or *BRCA2* mutation in tumor tissue from these patients.

Limitation: 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 a patient's blood sample. A negative result using the BRACAnalysis CDx blood test in prostate cancer patients does not rule out the possibility of a somatic *BRCA1* or *BRCA2* mutation in tumor tissue from these patients.

Notes



BRACAnalysis CDx[®]

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Learn more at:

myriad.com/oncology/BRACAnalysisCDx

1. Gradishar W, et al. Clinical variant classification: a comparison of public databases and a commercial testing laboratory. *Oncologist*. 2017;22(7):797-803. **2.** Referenced with permission from the NCCN: Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic. Version 2.2021. ©National Comprehensive Cancer Network, Inc. 2020. **3.** Internal data on file at Myriad Genetics, Inc.

Lynparza is a trademark of the AstraZeneca group of companies.

Talzenna is a trademark of Pfizer Inc. Rubraca is a trademark of Clovis Oncology.



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