BRACAnalysis CDx®

Germline Companion Diagnostic Test

Provider guide

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

Myriad genetics

Health. Illuminated.

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

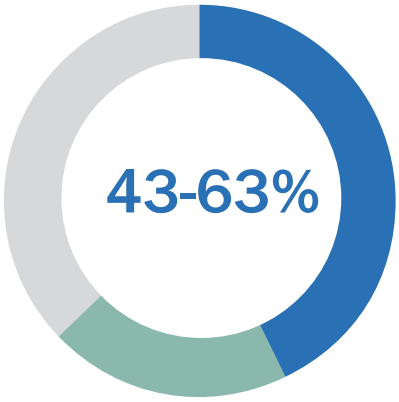
Accurate answers
FDA-approved with Medicare coverage

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 program[1]



VUS = variant of uncertain significance

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

- 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 *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)

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 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 Myriad[3]

≥90% Patients have or will qualify for a payment of $100 or less[3]

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)

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.

Notes

BRACAnalysis CDx®

Germline Companion Diagnostic Test

Learn more at https://myriad.com/genetic-tests/bracanalysiscdx-germline-test/

Myriad Oncology
320 Wakara Way
Salt Lake City, UT 84108
800-469-7423

SOURCES: 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.