A blood test to guide PARP inhibitor treatment decisions

CE IVD

BRACAnalysis® CDx

Companion Diagnostic Test

Myriad genetics

Myriad Genetic 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

EC REP
Myriad International GmbH
Nattermannallee 1
50829 Cologne, Germany

Affix one bar code label here

Test Request Form

- To avoid delays please complete entire form
- Please print all information in BLOCK LETTERS

Specimen collection date (required): (DD-MMM-YYYY) ☐☐ ☐☐ ☐☐☐☐

Specimen collected by (required)

Patient

Date of birth (DD-MMM-YYYY): ☐☐ ☐☐☐ ☐☐☐☐	
Sex assigned at birth: ☐ Female ☐ Male	Patient ID:
Legal name (Last):	
Legal name (First):	

Billing information

Payor ID: _____
or
research #: _____
or
voucher #: _____

Ordering physician

Last name:	Degree:
First name:	Clinical ID:
Institution:	
Street, nr:	
City, postal code:	Day phone:
Country:	Fax:
E-mail: _____	

Send results to (Optional – additional clinician can be listed to receive status updates and the patient's copy of the results)

Last name:	First name:	Institution:	
Street, nr:	City, postal code:	Country:	E-mail:

Test requested

CDxLab_BRACAnalysis - 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 specific therapies in accordance with the most recently approved therapeutic product labeling.

For more detailed information on the Myriad BRACAnalysis CDx test, please refer to the Technical Specifications.

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.

Ancestry (Select all that apply)

☐ Ashkenazi Jewish ☐ Asian ☐ Black / African ☐ Hispanic / Latino ☐ Middle Eastern ☐ Native American ☐ Pacific Islander ☐ White / Non-Hispanic

Patient personal history of cancer and other clinical information (Select all that apply)

☐ No personal history of cancer

Patient has been diagnosed with:		Age at diagnosis	Patient is currently being treated	Pathology / Other Info
☐ Breast cancer	☐ Left ☐ Right		☐	☐ Ductal invasive ☐ Lobular invasive ☐ DCIS ☐ Metastatic ☐ Bilateral ☐ Premenopausal ☐ Triple negative (ER-, PR-, HER2-)
☐ Ovarian cancer			☐	☐ Non-epithelial
☐ Prostate cancer			☐	Gleason Score _____ ☐ Metastatic
☐ Pancreatic cancer			☐	
☐ Hematologic cancer			☐	
☐ Other cancer(s) (e.g. cancers of the stomach, bile duct, kidney, ureter, brain, skin and others)			☐	Type: _____

Check if applicable to patient:

- ___% on one of the Lynch Syndrome Risk Models (PREMM$_5$, MMRpro, or MMRpredict)
- ☐ Bone Marrow transplant recipient Type: ☐ Autologous ☐ Allogeneic (if allogeneic please contact **helpmed@myriadgenetics.eu**)
- ☐ Blood transfusion recipient Type: ☐ Whole blood ☐ Packed red blood cells Date: (DD-MMM-YYYY) ☐☐ ☐☐☐ ☐☐☐☐

Cancel

Turn the page for additional patient information, test selection and authorized signature.

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Family history of cancer

☐ No known family history of cancer

Relationship to patient	Maternal (mother's side)	Paternal (father's side)	Cancer site	Age at each diagnosis
	☐	☐		
	☐	☐		
	☐	☐		
	☐	☐		
	☐	☐		

Authorized signature (Physician / healthcare provider)

I hereby authorize testing and confirm that informed consent has been obtained from the patient for blood to be sent to Myriad for analysis. I confirm that this test is medically necessary and results will be used in the medical management and treatment decisions for the patient. I hereby declare that the clinical information described on this Test Request Form is correct and belongs to the patient mentioned above. I hereby attest that the person listed in the ordering physician space above is authorized by law in the relevant jurisdiction to order the test requested herein.

_____
Ordering physician / healthcare provider's signature

Date (DD-MMM-YYYY) ☐☐ ☐☐☐ ☐☐☐☐
(Signature date is the specimen collection date if a different date is not provided above)

Cancel

Information

Sex assigned at birth is a label given to an individual at birth, typically "male" or "female".

A legal name identifies a person for legal and administrative purposes. It is recorded on a birth certificate, marriage certificate, or other government issued document that records a name change.

Internal use only: Bill Institution BIE _____ .

If previous genetic testing of one of the requested genes has been performed on this patient or a family member, the ordering physician or health care provider should inform the laboratory within two (2) business days of sending the specimen.

For information or questions regarding Myriad's privacy policy and technical specifications please visit our website: http://www.myriadgenetics.eu