MyChoice® CDx Plus

HRD Companion Diagnostic Test

Guiding PARP inhibitor treatment in ovarian cancer

Patient guide

Myriad genetics

Health. Illuminated.

Learn the HRD status of your ovarian cancer so you and your doctor can determine which treatment is right for you

What is next for your ovarian cancer?

Your experience of ovarian cancer is personal to you, and Myriad Genetics believes your treatment should be too. Powerful medicines called PARP inhibitors now exist which can slow or even shrink your tumors, and we can test to see if they could work for you.

Myriad Genetics' MyChoice CDx Plus HRD Companion Diagnostic Test is a type of DNA test to reveal if PARP inhibitor treatment is right for you.

What are PARP inhibitors?

PARP inhibitors are a type of oral medicine that blocks a DNA repair pathway in cancer cells.

Alone this isn't enough. Another pathway called homologous recombination (HR) also fixes DNA damage. The HR pathway is controlled by many genes, the most important being *BRCA1* and *BRCA2*. When the HR pathway is broken, for example due to a mutation in *BRCA1*, this is called HR deficiency (HRD).

In people who are HRD positive (HRD+), PARP inhibitors are more likely to work because without either of these DNA repair pathways working, the cancer cell dies.[1]

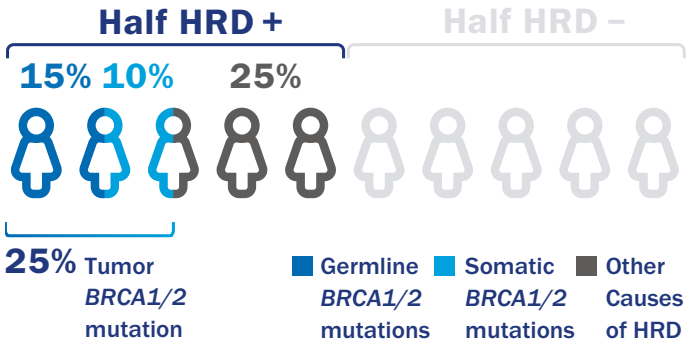
Around half of ovarian cancers are HRD positive (HRD+).[2]

To find out if you can benefit from PARP inhibitor treatment, you need to know your HRD status.

What is your HRD status?

You can find out your status by using the MyChoice CDx Plus test, which will measure your tumour for:

1. Mutations in *BRCA1* and *BRCA2* genes
2. Your genomic instability score — created by Myriad Genetics, this score shows how vulnerable your cancer is to HRD



MyChoice CDx Plus represents an important step forward in identifying more patients for treatment compared to traditional *BRCA* testing.

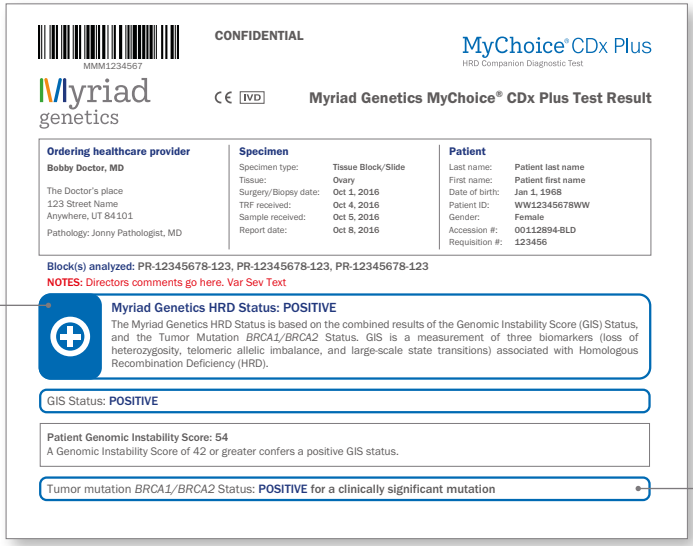
What do your results mean?

MyChoice CDx Plus provides clear answers to HRD status by giving you either a HRD- or HRD+ result.

- HRD- result means you are less likely to benefit from PARP inhibitor treatment. Your doctor will explain your options to you, which may still include going on one PARP inhibitor.
- HRD+ result means you should benefit from a wider range of PARP inhibitor treatments, and your doctor will discuss which one is best for you.

HRD Status: If the MyChoice CDx Plus test is positive, you are more likely to benefit from PARP inhibitor therapy.

Tumor Mutation: If a *BRCA* mutation is found in the tumor, you are more likely to benefit from PARP inhibitor therapy. This information will help your doctor discover whether the mutation is inherited with an additional blood test.



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MyChoice® CDx Plus
HRD Companion Diagnostic Test

Myriad genetics

CE IVD

Myriad Genetics MyChoice® CDx Plus Test Result

Ordering healthcare provider	Specimen		Patient	
Bobby Doctor, MD	Specimen type:	Tissue Block/Slide	Last name:	Patient last name
The Doctor's place	Tissue:	Ovary	First name:	Patient first name
123 Street Name	Surgery/Biopsy date:	Oct 1, 2016	Date of birth:	Jan 1, 1968
Anywhere, UT 84101	TRF received:	Oct 4, 2016	Patient ID:	WW12345678WW
Pathology: Jonny Pathologist, MD	Sample received:	Oct 5, 2016	Gender:	Female
	Report date:	Oct 8, 2016	Accession #:	00112894-BLD
			Requisition #:	123456

Block(s) analyzed: PR-12345678-123, PR-12345678-123, PR-12345678-123

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Myriad Genetics HRD Status: POSITIVE

The Myriad Genetics HRD Status is based on the combined results of the Genomic Instability Score (GIS) Status, and the Tumor Mutation *BRCA1/BRCA2* Status. GIS is a measurement of three biomarkers (loss of heterozygosity, telomeric allelic imbalance, and large-scale state transitions) associated with Homologous Recombination Deficiency (HRD).

GIS Status: **POSITIVE**

Patient Genomic Instability Score: 54
A Genomic Instability Score of 42 or greater confers a positive GIS status.

Tumor mutation *BRCA1/BRCA2* Status: **POSITIVE for a clinically significant mutation**

You can trust MyChoice CDx Plus

- Used in multiple clinical trials with PARP inhibitors
- Results within two weeks
- Reliably guides treatment for every woman[3]
- Recommended by international guidelines[4,5]

Myriad Genetics is committed to illuminating your pathway to the right treatment at the right time.

When will your treatment start?

We understand you want to start your treatment as soon as possible so it's important to get a quick result back from MyChoice CDx Plus. Fortunately, your doctor will receive the result in less than two weeks after we receive your sample, giving you time to make the right decision.

Does MyChoice CDx Plus tell you if your *BRCA* gene mutation was inherited?

Mutations found in tumors can either be inherited (germline) or occur only in the tumor (somatic), but current technology only allows us to tell that a mutation exists. Fortunately, a follow-up blood test can answer if the mutation is inherited and Myriad Genetics can help with this test. If your result has a mutation make sure to ask your doctor about next steps.

Do you need to get tested more than once?

No. You only needed to be tested once with MyChoice CDx Plus, and this result will help guide future treatment decisions.

What are the other causes of HRD?

There are many causes of HRD. The most common are mutations of the *BRCA* gene, which Myriad Genetics helped discover and which we test for with MyChoice CDx Plus. Other genes may also cause HRD and there are still many causes yet to be discovered. Myriad Genetics overcame this by developing a test that measures all the genetic damage created by these causes in the tumor. This way we don't miss undiscovered causes, and give you a better chance of a positive result.

Where can you find out more?

You can find out more on Myriad Genetics' genetic testing services and how they can help guide your ovarian cancer journey at our website **www.myriadgenetics.eu**

For more information on ovarian cancer in general, you can visit **www.cancerresearchuk.org**

References:

1. O'Connor, Mark J. "Targeting The DNA Damage Response In Cancer". *Molecular Cell*, vol 60, no. 4, 2015, pp. 547-560. *Elsevier BV*. 2. Moore, Kathleen N et al. "Niraparib Monotherapy For Late-Line Treatment Of Ovarian Cancer (QUADRA): A Multicentre, Open-Label, Single-Arm, Phase 2 Trial". *The Lancet Oncology*, vol 20, no. 5, 2019, pp. 636-648. *Elsevier BV*. 3. Ray-Coquard, Isabelle et al. "Olaparib Plus Bevacizumab As First-Line Maintenance In Ovarian Cancer". *New England Journal Of Medicine*, vol 381, no. 25, 2019, pp. 2416-2428. *Massachusetts Medical Society*. 4. Miller, R.E. et al. "ESMO Recommendations On Predictive Biomarker Testing For Homologous Recombination Deficiency And PARP Inhibitor Benefit In Ovarian Cancer". *Annals Of Oncology*, vol 31, no. 12, 2020, pp. 1606-1622. *Elsevier BV*. 5. Tew, William P. et al. "PARP Inhibitors In The Management Of Ovarian Cancer: ASCO Guideline". *Journal Of Clinical Oncology*, vol 38, no. 30, 2020, pp. 3468-3493. *American Society Of Clinical Oncology (ASCO)*.

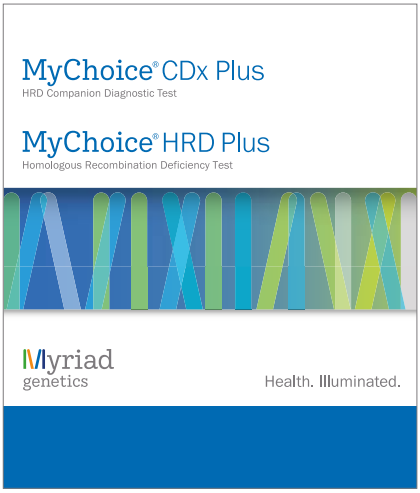
Myriad Genetics is committed to providing the right results at the right time so you can make the right decisions for your journey

About Myriad Genetics

Myriad Genetics is a leading genetic testing and precision medicine company dedicated to advancing health and wellbeing for all, empowering individuals with vital genetic insights and enabling doctors to better detect, treat and prevent disease.

Myriad Genetics is committed to illuminating the treatment pathway for every individual. Myriad discovers and provides genetic tests that determine the risk of developing disease, assess the risk of disease progression, and guide treatment decisions across medical specialties where critical genetic insights can significantly improve patient care and provide access to the right treatments.

For more information, visit the company's website:
www.myriadgenetics.eu



Intended use

Myriad Genetics MyChoice® CDx Plus is a next generation sequencing based in vitro diagnostic device that provides sequencing and large rearrangement analyses on a panel of genes and/or detects genomic instability using DNA extracted from tumor specimens. Homologous Recombination Deficiency (HRD) is determined by assessing the results of a subset of these genes and/or the Genomic Instability Score (GIS) Status. The test may be used as a companion diagnostic to identify patients who are or may become eligible for treatment with specific therapies in accordance with the approved therapeutic product labeling. Results are to be used by qualified health care professionals in accordance with professional guidelines in oncology for patients with malignant solid tumors.

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The Myriad Genetics MyChoice® CDx Plus 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, ISO 13485:2016 and ISO 15189: 2012 as applicable.

MyChoice CDx Plus Patient Brochure_02_22_EN PRD-1447 rev 00