MMM1234567

CONFIDENTIAL

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**
Anywere, 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

NOTES: Directors comments go here. Var Sev Text

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**

Gene	Clinically significant mutation(s)	Interpretation
BRCA1	c.68_69del (p.Glu23Valfs*17)	Deleterious
BRCA2	c.5946del (p.Ser1982Argfs*22)	Deleterious

Note: *This result represents findings from all analyzable regions. It may or may not reflect the germline status of this individual. Follow-up germline testing may be appropriate. In addition, the variants listed above may not be present in all tumor cells.*

Intended use

Myriad Genetics myChoice® CDx PLUS is used to detect Homologous Recombination Deficiency (HRD) by assessing the GIS Status and the Tumor Mutation *BRCA1/BRCA2* Status in genomic DNA extracted from tumor specimens. Results are used as an aid to determine the eligibility of patients with ovarian cancer for treatment with certain Poly-ADP Ribose Polymerase (PARP) inhibitors in accordance with the approved therapeutic product labeling.

When ordered as a panel, sequencing and large rearrangement analyses are also performed on all analyzable regions of the following genes that have been analytically validated using multiple cancer types: *ATM, BARD1, BRIP1, CDK12, CHEK1, CHEK2, FANCL, PALB2, PPP2R2A, RAD51B, RAD51C, RAD51D,* and *RAD54L*.

Gene	Additional mutation(s)	Interpretation
ATM	*ATM* var	*ATM Del*
RAD51D	c.68_69del (p.Glu23Valfs*17)	Deleterious

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

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Laboratory Director

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Myriad Genetics MyChoice® CDx Plus Test Result

Name: Jane5678901234567890 Doe45678901234567890 **DOB:** Jan 1, 1968 **Accession #:** 00112894-BLD **Report Date:** Oct 10, 2016

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

Details about identified mutation(s)

***BRCA1* c.68_69del (p.Glu23Valfs*17):** The *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). This is a common founder mutation in the Ashkenazi Jewish population (Struewing et al. Nat Genet 11: 198-200, 1995). However, this testing cannot determine if this mutation was inherited or was acquired somatically.

***BRCA2* c.5946del (p.Ser1982Argfs*22):** The *BRCA2* mutation c.5946del is predicted to result in the premature truncation of the *BRCA2* protein at amino acid position 2003 (p.Ser1982Argfs*22). This is a common founder mutation in the Ashkenazi Jewish population (Neuhausen et al. Nat Genet 13: 126-128, 1996). However, this testing cannot determine if this mutation was inherited or was acquired somatically.

***ATM* var:** This mutation ...

***RAD51D* var:** This mutation ...

Comprehensive gene analysis

Genes fully analyzed: *ATM, BARD1, BRCA1, BRCA2, BRIP1, CDK12, CHEK1, CHEK2, FANCL, PALB2, PPP2R2A, RAD51B, RAD51C, RAD51D, RAD54L*

Genes partially analyzed†:

Genes not analyzed:

† Complete analysis was not able to be performed on limited regions of specific genes, which shall be provided upon request.

Variant classification

Myriad Genetics' myVision® Variant Classification Program performs ongoing evaluations of variant classifications. When new evidence about a variant is identified and determined to result in clinical significance and management change, that information will automatically be made available to the healthcare provider through an amended report. The classification and interpretation of all variants identified in this assay reflects the current state of Myriad's scientific understanding at the time this report was issued. Variant classification and interpretation may change for a variety of reasons, including but not limited to, improvements to classification techniques, availability of additional scientific information, and observation of a variant in more patients. For more detailed information, please find the complete Technical Information at: http://bit.ly/MyriadTechInfo.

Assay description

The Myriad Genetics MyChoice® CDx Plus assay is a next generation sequencing-based *in vitro* diagnostic test that assesses the qualitative detection and classification of single nucleotide variants, insertions and deletions, and large rearrangement variants in protein coding regions and intron/exon boundaries of all genes analyzed and determines the Genomic Instability Score which is an algorithmic measurement of Loss of Heterozygosity (LOH), Telomeric Allelic Imbalance (TAI), and Large-scale State Transitions (LST) using DNA isolated from fixed tumor tissue specimens. For more detailed information, please find the complete Technical Information at: http://bit.ly/MyriadTechInfo.

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