MMM956400

CONFIDENTIAL

MyChoice® HRD Plus
Homologous Recombination Deficiency Test

Myriad Genetics MyChoice® HRD Plus Test Result

Ordering healthcare provider

Test HCP MD
Test Medical Center
123 MAIN ST
TESTVILLE, TX 55555

Pathology

Specimen

Specimen Type:	**Tissue**
Tissue:	**Ovary**
Surgery/Biopsy Date:	**Mar 3, 2022**
TRF Received:	**Mar 9, 2022**
Sample Received:	**Mar 9, 2022**
Report Date:	**Jun 3, 2022**

Patient

Last Name:	**Pt Last Name**
First Name:	**Pt First Name**
Date of Birth:	**Jan 1, 1968**
Patient ID:	**Patient id**
Gender:	**Female**
Accession #:	**07001741-BLD**
Requisition #:	**07001741**

Block(s) Analyzed:

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: 69
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.3689T>G (p.Leu1230*)	Deleterious
BRCA1	c.4912G>T (p.Glu1638*)	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® HRD 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. This test may aid in identifying patients with a positive HRD status, and should be used in accordance with the approved therapeutic product labeling.

Note: *The analytical assay used for MyChoice HRD Plus has been developed and validated in accordance with FDA Quality System Requirements (QSR) and is based on the same analytical assay used with the FDA approved MyChoice CDx test.*

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*. Results from these genes are provided for informational purposes only. Follow-up germline testing may be appropriate for mutations in genes associated with hereditary cancer risk.

Gene	Additional mutation(s)	Interpretation
ATM	c.1236-2A>T	Suspected Deleterious

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

Benjamin B. Roa, PhD
Diplomate ABMGG
Laboratory Director

Karla Bowles, PhD
Diplomate ABMGG
Laboratory Director

Myriad Genetics MyChoice® HRD Plus Test Result

Name: Pt First Name Pt Last Name **DOB:** Jan 1, 1968 **Accession #:** 07001741-BLD **Report Date:** Jun 3, 2022

Block(s) Analyzed:

Details about identified mutation(s)

***BRCA1* c.3689T>G (p.Leu1230*)** : The *BRCA1* mutation c.3689T>G is predicted to result in the premature truncation of the *BRCA1* protein at amino acid position 1230 (p.Leu1230*).

***BRCA1* c.4912G>T (p.Glu1638*)** : The *BRCA1* mutation c.4912G>T is predicted to result in the premature truncation of the *BRCA1* protein at amino acid position 1638 (p.Glu1638*).

***ATM* c.1236-2A>T** : The *ATM* mutation c.1236-2A>T is located 2 nucleotide(s) upstream of exon 9. This mutation occurs within a consensus splice junction, and it is predicted to result in abnormal mRNA splicing.

Additional non-clinically significant findings

One or more variants were identified in the tumor specimen. The names of these variants are being provided for informational purposes only. These variants are not known to be clinically actionable at this time. Medical management should not be based on this result.

Gene	Variant	Interpretation
BRCA2	c.7940T>C (p.Leu2647Pro)	Uncertain Significance

Details about non-clinically significant findings

***BRCA2* c.7940T>C (p.Leu2647Pro)** : The *BRCA2* variant c.7940T>C is predicted to result in the substitution of proline for leucine at amino acid position 2647 of the *BRCA2* protein (p.Leu2647Pro). There is some biochemical evidence to indicate that this variant disrupts normal protein function (Farrugia et al., Cancer Res 68:3523-3531, 2008; Guidugli et al., Am J Hum Genet 102:1-16, 2018).

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.

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Name: Pt First Name Pt Last Name **DOB:** Jan 1, 1968 **Accession #:** 07001741-BLD **Report Date:** Jun 3, 2022

Block(s) Analyzed:

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 HRD 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.