MMM5001184

Myriad genetics

CONFIDENTIAL

MyChoice® CDx
Myriad HRD Companion Diagnostic Test

Myriad MyChoice® CDx Test Result

ORDERING HEALTHCARE PROVIDER

PATHOLOGY

SPECIMEN

Specimen Type: **Tissue Block**
Tissue: **Ovary**
Surgery/Biopsy Date:
TRF Received:
Sample Received:
Report Date:

PATIENT

Legal Name:

Date of Birth:
Patient ID:
Sex at Birth: **F**
Accession #:
Requisition #:

Block(s) Analyzed:

Myriad HRD Status: POSITIVE

GIS Status: **POSITIVE**

The Genomic Instability Score (GIS) is a measurement of three biomarkers (loss of heterozygosity, telomeric allelic imbalance, and large-scale state transitions) associated with homologous recombination deficiency.

Tumor Mutation *BRCA1/BRCA2* Status: **NEGATIVE FOR A CLINICALLY SIGNIFICANT MUTATION**

ASSAY DESCRIPTION

Intended Use: Myriad MyChoice® CDx 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 the *BRCA1* and *BRCA2* genes and the determination of Genomic Instability Score (GIS) which is an algorithmic measurement of Loss of Heterozygosity (LOH), Telomeric Allelic Imbalance (TAI), and Large-scale State Transitions (LST) using DNA isolated from formalin-fixed paraffin embedded (FFPE) tumor tissue specimens. The results of the test are used as an aid in identifying ovarian cancer patients with positive homologous recombination deficiency (HRD) status, who are eligible, because of a positive test result for deleterious or suspected deleterious mutations in *BRCA1* or *BRCA2* genes, or may become eligible, because of a positive test result for deleterious or suspected deleterious mutations in *BRCA1* or *BRCA2* genes or a positive Genomic Instability Score, for treatment with the targeted therapy listed in Table 1 in accordance with the most recently approved therapeutic product labeling.

TABLE 1: Companion diagnostic indications

Tumor Type	Biomarker	Therapy
Ovarian Cancer	Myriad HRD, defined as: • deleterious or suspected deleterious mutations in *BRCA1* and *BRCA2* genes and/or • positive Genomic Instability Score	Lynparza® (olaparib)‡

‡ Refer to the drug label for HRD definition for olaparib monotherapy or combination therapy.

Detection of deleterious or suspected deleterious *BRCA1* and *BRCA2* mutations and/or positive Genomic Instability Score in ovarian cancer patients is also associated with enhanced progression-free survival (PFS) from Zejula® (niraparib) maintenance therapy in accordance with the most recently approved therapeutic product labeling. This assay is for professional use only and is to be performed only at Myriad Genetic Laboratories, Inc., a single laboratory site located at 320 Wakara Way, Salt Lake City, UT 84108.

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

Benjamin B. Roa, PhD
Diplomate ABMGG
Laboratory Director

Karla Bowles, PhD
Diplomate ABMGG
Laboratory Director

Myriad MyChoice® CDx Test Result

Name: **DOB:** **Accession #:** **Report Date:**

Block(s) Analyzed:

THE FOLLOWING INFORMATION HAS NOT BEEN REVIEWED AND APPROVED BY THE FDA.

COMPREHENSIVE GENE ANALYSIS

Genes Fully Analyzed: *BRCA1, BRCA2*

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.

Patient Genomic Instability Score: 78
A Genomic Instability Score (GIS) of 42 or greater confers a positive GIS status.

VARIANT CLASSIFICATION AND ANALYSIS DESCRIPTION

Myriad's 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 including Performance Characteristics, please find the complete Technical Information at: bit.ly/myChoiceCDxSpecs.

Sex assigned at birth refers to the classification of an individual as male or female, often based on physical characteristics at birth.