MMM523294

CONFIDENTIAL

MYRIAD myChoice® CDx

Myriad myChoice® CDx Test Result

ORDERING HEALTHCARE PROVIDER

Bobby Doctor PhD
The Doctor's Place
123 Street Name
Anywhere, UT 84101

PATHOLOGIST

Jonny Pathologist PhD

SPECIMEN

Specimen Type:	**Tissue Block**
Tissue:	**Breast**
Surgery/Biopsy Date:	**Mar 13, 2019**
TRF Received:	**Oct 1, 2019**
Sample Received:	**Oct 1, 2019**
Report Date:	**Oct 23, 2019**

PATIENT

Last Name:	**Pt Last Name**
First Name:	**Pt First Name**
Date of Birth:	**Jan 7, 1967**
Patient ID:	**Patient id**
Gender:	**Female**
Accession #:	**08000148-BLD**
Requisition #:	**08000148**

Block(s) Analyzed: **132test-1**

Myriad myChoice® CDx Status: POSITIVE

Genomic Instability Status: **POSITIVE**

The Genomic Instability Score 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: **POSITIVE FOR A CLINICALLY SIGNIFICANT MUTATION**

GENE	CLINICALLY SIGNIFICANT MUTATION(S)	INTERPRETATION
BRCA1	c.2433del (p.Lys812Argfs*3)	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.

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 for treatment with the targeted therapy listed in Table 1 in accordance with the 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)	Zejula® (niraparib)

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

Hillary Zalaznick, MD
Diplomate FCAP
Laboratory Director
Anatomic Pathology

Myriad myChoice® CDx Test Result

Name: Pt First Name Pt Last Name **DOB:** Jan 7, 1967 **Accession #:** 08000148-BLD **Report Date:** Oct 23, 2019

Block(s) Analyzed: **132test-1**

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

DETAILS ABOUT IDENTIFIED MUTATION(S)

***BRCA1* c.2433del (p.Lys812Argfs*3)** : The *BRCA1* mutation c.2433del is predicted to result in the premature truncation of the *BRCA1* protein at amino acid position 814 (p.Lys812Argfs*3).

COMPREHENSIVE GENE ANALYSIS

Genes Fully Analyzed: *BRCA1, BRCA2*

Genes Partially Analyzed †**:**

Genes Not Analyzed:

† Specific gene regions that were not able to be analyzed may be provided upon request.

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

Myriad Genetic Laboratories, Inc. | 320 Wakara Way, Salt Lake City, Utah 84108 | PH: 877-283-6709 FX: 801-883-8998