MI PROFILE™

Final Report | CARIS LIFE SCIENCES

Patient

Name: Patient, Test
Date of Birth: XX/Mon/19XX
Sex: Female
Case Number: TN19-XXXXXX
Diagnosis: Carcinoma, metastatic, NOS

Specimen Information

Primary Tumor Site: Breast, NOS
Specimen Site: Pleura, NOS
Specimen ID: ABC-1234-XYZ
Specimen Collected: XX-Mon-2019
Completion of Testing: XX-Mon-2019

Ordered By

Ordering Physician, MD
Cancer Center
123 Main Street
Springfield, XY 12345, USA
1 (123) 456-7890

High Impact Results

BIOMARKER	METHOD	RESULT	THERAPY ASSOCIATION		BIOMARKER LEVEL*
BRCA1	**NGS**	**Mutated, Pathogenic Exon 23 | p.R1835***	**BENEFIT**	**olaparib, talazoparib**	**Level 1**
			BENEFIT	carboplatin, cisplatin	Level 3A
ER	**IHC**	**Positive | 3+, 90%**	**BENEFIT**	**endocrine therapy**	**Level 1**
			BENEFIT	abemaciclib, palbociclib, ribociclib	Level 2
			BENEFIT	everolimus	Level 2
PR	**IHC**	**Positive | 2+, 3%**	**BENEFIT**	**endocrine therapy**	**Level 1**
			BENEFIT	abemaciclib, palbociclib, ribociclib	Level 2
ERBB2 (Her2/Neu)	CISH	Not Amplified	LACK OF BENEFIT	ado-trastuzumab emtansine (T-DM1), lapatinib, neratinib, pertuzumab, trastuzumab	Level 1
	IHC	Negative | 1+, 10%			

* Biomarker reporting classification: Level 1 - highest level of clinical evidence and/or biomarker association included on the drug label; Level 2 - strong evidence of clinical significance and is endorsed by standard clinical guidelines; Level 3 - potential clinical significance (3A - evidence exists in patient's tumor type, 3B - evidence exists in another tumor type).

Additional Results

CANCER TYPE RELEVANT BIOMARKERS

Biomarker	Method	Result
MSI	NGS	Stable
Mismatch Repair Status		Proficient
Tumor Mutational Burden		Intermediate | 11 Mutations/Mb
AKT1	NGS	Mutation Not Detected
AR	IHC	Positive | 2+, 90%
BRCA2	NGS	Mutation Not Detected
ERBB2 (Her2/Neu)	NGS	Mutation Not Detected
ESR1	NGS	Mutation Not Detected
PD-L1	SP142 IHC	Negative | 0

CANCER TYPE RELEVANT BIOMARKERS (cont)

Biomarker	Method	Result
PIK3CA	NGS	Mutated, Pathogenic
		Exon 21 | p.H1047R
PTEN	IHC	Positive | 1+, 100%
	NGS	Mutation Not Detected

OTHER FINDINGS (see page 2 for additional results)

Biomarker	Method	Result
ARID1A	NGS	Mutated, Pathogenic
		Exon 3 | p.P517fs

The selection of any, all, or none of the matched therapies resides solely with the discretion of the treating physician. Decisions on patient care and treatment must be based on the independent medical judgment of the treating physician, taking into consideration all available information concerning the patient's condition, the FDA prescribing information for any therapeutic, and in accordance with the applicable standard of care. Whether or not a particular patient will benefit from a selected therapy is based on many factors and can vary significantly. All trademarks and registered trademarks are the property of their respective owners.

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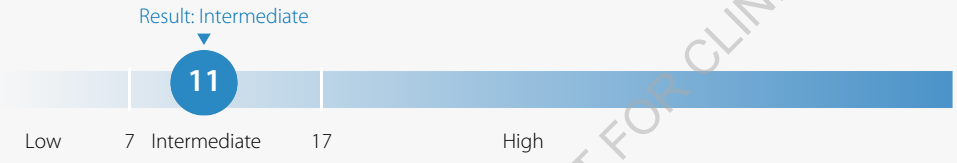
Biomarker Results

This summary includes biomarkers most commonly associated with cancer. Complete details of all biomarkers tested can be found in the Appendix.

GENOMIC SIGNATURES		
Biomarker	**Method**	**Result**
Microsatellite Instability (MSI)	NGS	Stable
Tumor Mutational Burden (TMB)	NGS	

GENES TESTED WITH MUTATIONS/ALTERATIONS						
Gene	**Method**	**Variant Interpretation**	**Protein Alteration**	**Exon**	**DNA Alteration**	**Variant Frequency %**
ARID1A	NGS	Mutated, Variant of Unknown Significance	p.P329S	1	c.985C>T	67
	NGS	Mutated, Pathogenic	p.P517fs	3	c.1548 _1549delTC	46
ATM	NGS	Mutated, Presumed Benign	p.I124V	5	c.370A>G	25
BRCA1	NGS	Mutated, Pathogenic	p.R1835*	23	c.5503C>T	52
CDH1	NGS	Mutated, Variant of Unknown Significance	p.V132I	4	c.394G>A	24
PIK3CA	NGS	Mutated, Pathogenic	p.H1047R	21	c.3140A>G	34
RET	NGS	Mutated, Variant of Unknown Significance	p.T75M	2	c.224C>T	35

Unclassified alterations for DNA sequencing can be found in the Appendix.
Formal nucleotide nomenclature and gene reference sequences can be found in the appendix of this report.

Transcript ID and Variants of Unknown Significance can be found in the Appendix.

Other Findings

IMMUNOHISTOCHEMISTRY (IHC)			
Biomarker	**Result**	**Biomarker**	**Result**
AR	Positive | 2+, 90%	PD-L1 (SP142)	Negative | 0
ER	Positive | 3+, 90%	PMS2	Positive | 1+, 5%
ERBB2 (Her2/Neu)	Negative | 1+, 10%	PR	Positive | 2+, 3%
MLH1	Positive | 1+, 20%	PTEN	Positive | 1+, 100%
MSH2	Positive | 1+, 30%	TrkA/B/C	Negative | 0
MSH6	Positive | 1+, 20%		

Additional results continued on the next page. >

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Clinical Trials Connector™

For a complete list of open, enrolling clinical trials visit MI Portal to access the **Clinical Trials Connector**. This personalized, real-time web-based service provides additional clinical trial information and enhanced searching capabilities, including, but not limited to:

- Location: filter by geographic area
- Biomarker(s): identify specific biomarkers associated with open clinical trials to choose from
- Drug(s): search for specific therapies
- Trial Sponsor: locate trials based on the organization supporting the trial(s)

Visit www.CarisMolecularIntelligence.com to view all matched trials. Therapeutic agents listed below may or may not be currently FDA approved for the tumor type tested.

CHEMOTHERAPY CLINICAL TRIALS (275)			
Drug Class	**Biomarker**	**Method**	**Investigational Agent(s)**
Anti-androgens (15)	AR	IHC	TAK-700, abiraterone, bicalutamide, enzalutamide
Anti-hormonal therapy (155)	ER	IHC	GTx024, TAK-700, abiraterone, anastrozole, bicalutamide, enzalutamide, exemestane, fulvestrant, goserelin, letrozole, leuprolide, tamoxifen, toremifene
	PR	IHC	
	AR	IHC	
Anti-inflammatory agents (1)	PIK3CA	NGS	aspirin
DNA minor groove binding agents (2)	BRCA1	NGS	PM01183 (lurbinectedin)
Platinum compounds (102)	BRCA1	NGS	carboplatin, cisplatin, oxaliplatin

TARGETED THERAPY CLINICAL TRIALS (417)			
Drug Class	**Biomarker**	**Method**	**Investigational Agent(s)**
Akt inhibitors (13)	ARID1A	NGS	ARQ092, AZD5363, MK2206, ipatasertib, triciribine
Chk1/Chk2 inhibitors (5)	BRCA1	NGS	LY2606368
Immunomodulatory agents (246)	AR	IHC	MEDI4736, MK-3475, MPDL3280A, MSB0010718C, atezolizumab, avelumab, durvalumab, nivolumab, pembrolizumab
Multikinase inhibitors (24)	RET	NGS	MGCD516, cabozantinib, lenvatinib, regorafenib, sorafenib, sunitinib, vandetanib
PARP inhibitors (61)	BRCA1	NGS	BMN-673, MK4827, niraparib, olaparib, rucaparib, talazoparib, veliparib
PI3K/Akt/mTor inhibitors (68)	PIK3CA	NGS	ARQ092, AZD2014, AZD5363, BAY80-6946, BYL719, GSK2636771, INK1117, MK2206, MLN0128, MLN1117, PF-05212384, everolimus, ipatasertib, sirolimus, taselisib, temsirolimus, triciribine

( ) = represents the total number of clinical trials identified by the Clinical Trials Connector for the provided drug class or table.

Please refer to the "Notes of Significance" section that may contain additional information regarding therapy associations.

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To view the rest of the report, contact a Caris Molecular Intelligence® representative today.

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