MI PROFILE™
MOLECULAR INTELLIGENCE TUMOR REPORT

CARIS® LIFE SCIENCES

FINAL REPORT

PATIENT

Name: Patient, Test
Date of Birth:
Sex: Male
Case Number: TN14-111111
Diagnosis: Adenocarcinoma, pancreatobiliary type

SPECIMEN INFORMATION

Primary Tumor Site: Pancreas, NOS
Specimen Site: Lower lobe, lung
Specimen ID: ABC-12345-YZ
Specimen Collected: XX-Mon-2015
Completion of Testing: XX-Mon-2015

ORDERED BY

Ordering Physician, MD
The Cancer Center
123 Main Street
Springfield, XY 123345
(123) 456-7890

Bold Therapies = On NCCN Compendium® Therapies

✔ THERAPIES WITH **POTENTIAL BENEFIT** (PAGE 3)

capecitabine, fluorouracil	TS★
docetaxel	TUBB3, TLE3, PGP
gemcitabine	RRM1★
paclitaxel	TUBB3, TLE3, PGP
pemetrexed	TS★

★ **Indicates Clinical Trial Opportunity • 213 Chemotherapy Trials • 89 Targeted Therapy Trials** *(See Clinical Trials Connector™ on page 7 for details.)*

✘ THERAPIES WITH **POTENTIAL LACK OF BENEFIT** (PAGE 4)

irinotecan	TOPO1
abarelix, degarelix, goserelin, leuprolide, triptorelin	ER, PR, Androgen Receptor
abiraterone, bicalutamide, enzalutamide, flutamide	Androgen Receptor
ado-trastuzumab emtansine (T-DM1), pertuzumab, trastuzumab	Her2/Neu
anastrozole, exemestane, fulvestrant, letrozole, megestrol acetate, tamoxifen, toremifene	PR, ER
dabrafenib, vemurafenib	BRAF
dacarbazine, temozolomide	MGMT
doxorubicin, epirubicin, liposomal-doxorubicin	PGP, Her2/Neu, TOP2A
lapatinib	Her2/Neu
topotecan	TOPO1

? THERAPIES WITH **INDETERMINATE BENEFIT** (PAGE 6)

cisplatin, oxaliplatin	carboplatin	imatinib
nab-paclitaxel	everolimus, temsirolimus	vandetanib

SAMPLE REPORT. ILLUSTRATIVE PURPOSES ONLY. NOT FOR CLINICAL USE.

Therapies associated with potential benefit or lack of benefit, as indicated above, are based on biomarker results provided in this report and are based on published medical evidence. This evidence may have been obtained from studies performed in the cancer type present in the tested patient's sample or derived from another tumor type. 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 in addition to this report concerning the patient's condition in accordance with the applicable standard of care.

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SUMMARY OF BIOMARKER RESULTS (SEE APPENDIX FOR FULL DETAILS)

Biomarker	Method	Result	Biomarker	Method	Result
ABL1	NGS	Mutation Not Detected	IDH1	NGS	Mutation Not Detected
AKT1	NGS	Mutation Not Detected	JAK2	NGS	Mutation Not Detected
ALK	NGS	Mutation Not Detected	KDR (VEGFR2)	NGS	Mutation Not Detected
Androgen Receptor	IHC	Negative	KRAS	NGS	Mutated | G12R
APC	NGS	Mutation Not Detected	MGMT	IHC	Positive
ATM	NGS	Mutation Not Detected	MPL	NGS	Mutation Not Detected
BRAF	NGS	Mutation Not Detected	NOTCH1	NGS	Mutation Not Detected
BRCA1	NGS	Mutation Not Detected	NRAS	NGS	Mutation Not Detected
BRCA2	NGS	Mutation Not Detected	PD-1 IHC	IHC	Positive
c-KIT	NGS	Mutation Not Detected	PDGFRA	NGS	Mutation Not Detected
cMET	IHC	Negative	PD-L1 IHC	IHC	Negative
cMET	NGS	Mutation Not Detected	PGP	IHC	Positive
cMET	CISH	Not Amplified	PIK3CA	NGS	Mutation Not Detected
CSF1R	NGS	Mutation Not Detected	PR	IHC	Negative
CTNNB1	NGS	Mutation Not Detected	PTEN	IHC	Negative
EGFR	IHC	Positive	PTEN	NGS	Mutation Not Detected
EGFR	NGS	Mutation Not Detected	RET	NGS	Mutation Not Detected
ER	IHC	Negative	RRM1	IHC	Negative
FGFR1	NGS	Mutation Not Detected	SMO	NGS	Mutation Not Detected
FGFR2	NGS	Mutation Not Detected	SPARC Monoclonal	IHC	Negative
FLT3	NGS	Mutation Not Detected	SPARC Polyclonal	IHC	Negative
GNA11	NGS	Mutation Not Detected	TLE3	IHC	Negative
GNAQ	NGS	Mutation Not Detected	TOP2A	IHC	Negative
GNAS	NGS	Mutation Not Detected	TOPO1	IHC	Negative
Her2/Neu	IHC	Equivocal	TP53	NGS	Mutated | P278S
Her2/Neu	CISH	Not Amplified	TS	IHC	Negative
Her2/Neu (ERBB2)	NGS	Mutation Not Detected	TUBB3	IHC	Negative
HRAS	NGS	Mutation Not Detected	VHL	NGS	Mutation Not Detected

IHC: Immunohistochemistry **CISH:** Chromogenic *in situ* hybridization **NGS:** Next-Generation Sequencing

For Next-Generation Sequencing, a total of 35 genes were analyzed. The results above include genes most commonly associated with cancer and any additional mutations identified. No alterations were identified in 33 genes. For a complete list of genes tested, visit www.CarisMolecularIntelligence.com/profilemenu.

See the Appendix section for a detailed overview of the biomarker test results for each technology.

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✔ THERAPIES WITH **POTENTIAL BENEFIT**

Therapies	Test	Method	Result	Value†	Clinical Association				
					Potential Benefit	Decreased Potential Benefit	Lack of Potential Benefit	Highest Level of Evidence*	Reference
capecitabine, fluorouracil, pemetrexed	TS	IHC	Negative	1+ 6%	✔			I / Good	24, 25, 26
docetaxel, paclitaxel	PGP	IHC	Positive	2+ 12%		✔		II-3 / Fair	42, 43
	TLE3	IHC	Negative	2+ 25%		✔		II-2 / Good	41
	TUBB3	IHC	Negative	2+ 15%	✔			I / Good	37, 38, 39, 40
gemcitabine	RRM1	IHC	Negative	2+ 5%	✔			I / Good	53

* The level of evidence for all references is assigned according to the Literature Level of Evidence Framework consistent with the US Preventive Services Task Force described further in the Appendix of this report. The data level of each biomarker-drug interaction is the highest level of evidence based on the body of evidence, overall clinical utility, competing biomarker interactions and tumor type from which the evidence was gathered.

†Refer to Appendix for detailed Result and Value information for each biomarker, including appropriate cutoffs, unit of measure, etc.

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✘ THERAPIES WITH **POTENTIAL LACK OF BENEFIT**

Therapies	Test	Method	Result	Value†	Clinical Association				
					Potential Benefit	Decreased Potential Benefit	Lack of Potential Benefit	Highest Level of Evidence*	Reference
abarelix, degarelix, goserelin, leuprolide, triptorelin	Androgen Receptor	IHC	Negative	0+ 100%			✔	II-3 / Good	2
	ER	IHC	Negative	0+ 100%			✔	I / Good	1
	PR	IHC	Negative	0+ 100%			✔	I / Good	1
abiraterone, bicalutamide, enzalutamide, flutamide	Androgen Receptor	IHC	Negative	0+ 100%			✔	I / Good	2, 3, 4, 5
ado-trastuzumab emtansine (T-DM1), pertuzumab, trastuzumab	Her2/Neu	CISH	Not Amplified	1.19			✔	I / Good	6, 7, 8, 9, 10, 11, 12, 13
	Her2/Neu	IHC	Equivocal	2+ 20%				I / Good	6, 7, 8, 9, 10, 12, 13
anastrozole, exemestane, fulvestrant, letrozole, megestrol acetate, tamoxifen, toremifene	ER	IHC	Negative	0+ 100%			✔	I / Good	14, 17, 18, 19, 20, 21, 22, 23
	PR	IHC	Negative	0+ 100%			✔	I / Good	14, 15, 16, 17, 18, 19, 20, 21
dabrafenib, vemurafenib	BRAF	Next Gen SEQ	Wild Type				✔	I / Good	31, 32, 33, 34
dacarbazine, temozolomide	MGMT	IHC	Positive	2+ 90%			✔	II-2 / Good	35, 36
doxorubicin, epirubicin, liposomal-doxorubicin	Her2/Neu	CISH	Not Amplified	1.19			✔	I / Good	46, 47
	PGP	IHC	Positive	2+ 12%			✔	II-1 / Fair	44, 45
	TOP2A	IHC	Negative	2+ 1%			✔	I / Good	48, 49
irinotecan, topotecan	TOPO1	IHC	Negative	1+ 2%			✔	II-1 / Good	59, 60, 61

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Additional Therapies Associated with Potential Lack of Benefit continued on the next page. >

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? THERAPIES WITH **INDETERMINATE BENEFIT**

(Biomarker results do not impact potential benefit or lack of potential benefit)

Therapies	Test	Method	Result	Value†	Clinical Association				
					Potential Benefit	Decreased Potential Benefit	Lack of Potential Benefit	Highest Level of Evidence*	Reference
carboplatin, cisplatin, oxaliplatin	BRCA1	Next Gen SEQ	Mutation Not Detected				✔	II-2 / Good	27, 28, 29, 30
	BRCA2	Next Gen SEQ	Mutation Not Detected				✔	II-2 / Good	27, 28, 29
everolimus, temsirolimus	PIK3CA	Next Gen SEQ	Wild Type			✔		II-2 / Good	50, 51, 52
imatinib	c-KIT	Next Gen SEQ	Wild Type				✔	II-2 / Good	54, 55
	PDGFRA	Next Gen SEQ	Wild Type				✔	II-3 / Good	56, 57, 58
nab-paclitaxel	SPARC Monoclonal	IHC	Negative	2+ 10%			✔	II-2 / Good	65, 66#
	SPARC Polyclonal	IHC	Negative	2+ 5%			✔	II-2 / Good	65, 66#
vandetanib	RET	Next Gen SEQ	Wild Type					I / Good	67

* The level of evidence for all references is assigned according to the Literature Level of Evidence Framework consistent with the US Preventive Services Task Force described further in the Appendix of this report. The data level of each biomarker-drug interaction is the highest level of evidence based on the body of evidence, overall clinical utility, competing biomarker interactions and tumor type from which the evidence was gathered.

Evidence reference includes data from the same lineage as the tested specimen.

†Refer to Appendix for detailed Result and Value information for each biomarker, including appropriate cutoffs, unit of measure, etc.

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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.

CHEMOTHERAPY CLINICAL TRIALS (213)

Drug Class	Biomarker	Method	Investigational Agent(s)
Antifolates (2)	TS	IHC	methotrexate
Nucleoside analog (126)	RRM1	IHC	gemcitabine
Pyrimidine analog (85)	TS	IHC	capecitabine, fluorouracil

TARGETED THERAPY CLINICAL TRIALS (89)

Drug Class	Biomarker	Method	Investigational Agent(s)
Cell cycle inhibitors (3)	TP53	Next Gen SEQ	MK-1775
EGFR monoclonal antibody (16)	EGFR	IHC	cetuximab
ERK inhibitors (1)	KRAS	Next Gen SEQ	BVD-523
Immunomodulatory agents (3)	PD-1	IHC	MK-3475, lambrolizumab, lambrolizumab (MK-3475)
MEK inhibitors (2)	KRAS	Next Gen SEQ	GDC-0973
PARP inhibitors (2)	PTEN	IHC	BMN-673
PI3K/Akt/mTor inhibitors (62)	PTEN	IHC	ARQ092, AZD2014, AZD5363, BAY80-6946, BEZ235, BKM120, BYL719, CC-223, GDC-0068, GSK2110183, GSK2141795, INK1117, LY2780301, MK2206, MLN0128, MLN1117, everolimus

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

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

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