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, NOS

SPECIMEN INFORMATION

Primary Tumor Site: Lung, NOS
Specimen Site: Lung, NOS
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 12345
(123) 456-7890

Bold Therapies = On NCCN Compendium® Therapies

✔ THERAPIES WITH **POTENTIAL BENEFIT** (PAGE 4)

afatinib	EGFR★
docetaxel, paclitaxel	PGP, TUBB3, TLE3★
erlotinib	PTEN, KRAS, cMET, PIK3CA, EGFR★
gemcitabine	RRM1★
irinotecan	TOPO1
nab-paclitaxel	SPARC Polyclonal, SPARC Monoclonal
pemetrexed	TS★
capecitabine, fluorouracil	TS★
dacarbazine, temozolomide	MGMT★
doxorubicin, epirubicin, liposomal-doxorubicin	PGP, TOP2A, Her2/Neu
gefitinib	PTEN, KRAS, cMET, PIK3CA, EGFR★

★ **Indicates Clinical Trial Opportunity • 116 Chemotherapy Trials • 106 Targeted Therapy Trials** *(See Clinical Trials Connector™ on page 8 for details.)*

✘ THERAPIES WITH **POTENTIAL LACK OF BENEFIT** (PAGE 6)

ceritinib	ALK
crizotinib	ROS1, ALK
dabrafenib, vemurafenib	BRAF
cetuximab	EGFR

? THERAPIES WITH **INDETERMINATE BENEFIT** (PAGE 7)

trastuzumab†	
ado-trastuzumab emtansine (T-DM1)†, pertuzumab†	
everolimus, temsirolimus	
imatinib	
lapatinib†	
vandetanib	

†Association to Benefit was not indicated due to assay failure.

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
ABL1	NGS	Mutation Not Detected
AKT1	NGS	Quantity Not Sufficient
ALK	NGS	Mutation Not Detected
ALK	FISH	Negative
Androgen Receptor	IHC	Negative
APC	NGS	Mutation Not Detected
ATM	NGS	Mutation Not Detected
BRAF	NGS	Mutation Not Detected
CDH1	NGS	Mutation Not Detected
c-KIT	NGS	Mutation Not Detected
cMET	CISH	Test Not Performed
cMET	IHC	Negative
cMET	NGS	Mutation Not Detected
CSF1R	NGS	Mutation Not Detected
CTNNB1	NGS	Mutation Not Detected
EGFR	NGS	Mutated | L858R
EGFR	IHC (H-Score)	Negative
ER	IHC	Negative
ERBB4	NGS	Mutation Not Detected
FBXW7	NGS	Mutation Not Detected
FGFR1	NGS	Mutation Not Detected
FGFR2	NGS	Mutation Not Detected
FLT3	NGS	Mutation Not Detected
GNA11	NGS	Quantity Not Sufficient
GNAQ	NGS	Mutation Not Detected
GNAS	NGS	Mutation Not Detected
Her2/Neu	CISH	Test Not Performed
Her2/Neu	IHC	Negative
Her2/Neu (ERBB2)	NGS	Mutation Not Detected
HNF1A	NGS	Mutation Not Detected
HRAS	NGS	Quantity Not Sufficient
IDH1	NGS	Mutation Not Detected
JAK2	NGS	Mutation Not Detected
JAK3	NGS	Mutation Not Detected

Biomarker	Method	Result
KDR (VEGFR2)	NGS	Mutation Not Detected
KRAS	NGS	Mutation Not Detected
MGMT	IHC	Negative
MPL	NGS	Mutation Not Detected
NOTCH1	NGS	Mutation Not Detected
NPM1	NGS	Mutation Not Detected
NRAS	NGS	Mutation Not Detected
PD-1 IHC	IHC	Negative
PDGFRA	NGS	Mutation Not Detected
PD-L1 IHC	IHC	Negative
PGP	IHC	Negative
PIK3CA	NGS	Mutation Not Detected
PR	IHC	Negative
PTEN	NGS	Mutation Not Detected
PTEN	IHC	Positive
PTPN11	NGS	Mutation Not Detected
RB1	NGS	Mutation Not Detected
RET	NGS	Mutation Not Detected
ROS1	FISH	Negative
RRM1	IHC	Negative
SMAD4	NGS	Mutation Not Detected
SMARCB1	NGS	Mutation Not Detected
SMO	NGS	Quantity Not Sufficient
SPARC Monoclonal	IHC	Negative
SPARC Polyclonal	IHC	Positive
STK11	NGS	Quantity Not Sufficient
TLE3	IHC	Positive
TOP2A	IHC	Positive
TOPO1	IHC	Positive
TP53	NGS	Mutated | V173L
TS	IHC	Negative
TUBB3	IHC	Positive
VHL	NGS	Quantity Not Sufficient

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

Biomarker Results continued on the next page. >

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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
afatinib	EGFR	Next Gen SEQ	Mutated, Pathogenic	L858R	✔			I / Good	4#
capecitabine, fluorouracil, pemetrexed	TS	IHC	Negative	1+ 1%	✔			II-1 / Good	5#, 6#, 7
dacarbazine, temozolomide	MGMT	IHC	Negative	1+ 10%	✔			II-2 / Good	19, 20
docetaxel, paclitaxel	PGP	IHC	Negative	0+ 100%	✔			II-3 / Fair	21, 22#
	TLE3	IHC	Positive	2+ 30%	✔			II-2 / Good	27
	TUBB3	IHC	Positive	3+ 90%		✔		I / Good	23, 24#, 25#, 26#
doxorubicin, epirubicin, liposomal-doxorubicin	Her2/Neu	CISH	Technical Issues						
	PGP	IHC	Negative	0+ 100%	✔			II-1 / Fair	28, 29
	TOP2A	IHC	Positive	2+ 10%	✔			I / Good	30, 31
erlotinib, gefitinib	cMET	CISH	Technical Issues						
	EGFR	Next Gen SEQ	Mutated, Pathogenic	L858R	✔			I / Good	33#, 37#, 38#, 39#
	KRAS	Next Gen SEQ	Wild Type		✔			I / Good	33#, 34#
	PIK3CA	Next Gen SEQ	Wild Type		✔			II-1 / Good	35#, 36#
	PTEN	IHC	Positive	2+ 95%	✔			II-3 / Fair	32#
gemcitabine	RRM1	IHC	Negative	2+ 15%	✔			I / Good	43#
irinotecan	TOPO1	IHC	Positive	2+ 80%	✔			II-1 / Good	49, 50, 51

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

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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
nab-paclitaxel	SPARC Monoclonal	IHC	Negative	2+ 10%		✔		II-2 / Good	55, 56
	SPARC Polyclonal	IHC	Positive	2+ 30%	✔			II-2 / Good	55, 56

* 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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✘ 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
ceritinib	ALK	FISH	Negative				✔	II-1 / Good	8#
cetuximab	EGFR	IHC H-Score	Negative	180			✔	I / Good	9#
crizotinib	ALK	FISH	Negative				✔	I / Good	13#, 14
	ROS1	FISH	Negative				✔	III / Good	10#, 11#, 12#
dabrafenib, vemurafenib	BRAF	Next Gen SEQ	Wild Type				✔	I / Good	15#, 16, 17#, 18

* 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.

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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
ado-trastuzumab emtansine (T-DM1), pertuzumab	Her2/Neu	CISH	Technical Issues						
	Her2/Neu	IHC	Negative	0+ 100%			✔	I / Good	1, 2, 3
everolimus, temsirolimus	PIK3CA	Next Gen SEQ	Wild Type			✔		II-2 / Good	40, 41, 42
imatinib	c-KIT	Next Gen SEQ	Wild Type				✔	II-2 / Good	44, 45
	PDGFRA	Next Gen SEQ	Wild Type				✔	II-3 / Good	46, 47, 48
lapatinib	Her2/Neu	CISH	Technical Issues						
	Her2/Neu	IHC	Negative	0+ 100%			✔	I / Good	52, 53, 54
trastuzumab	Her2/Neu	CISH	Technical Issues						
	Her2/Neu	IHC	Negative	0+ 100%			✔	I / Good	59, 60, 61, 62
	Her2/Neu (ERBB2)	Next Gen SEQ	Wild Type				✔	II-3 / Good	57#, 58#
vandetanib	RET	Next Gen SEQ	Wild Type					I / Good	63

* 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 (116)

Drug Class	Biomarker	Method	Investigational Agent(s)
Alkylating agents (1)	MGMT	IHC	dacarbazine
Antifolates (1)	TS	IHC	methotrexate
Nucleoside analog (46)	RRM1	IHC	gemcitabine
Pyrimidine analog (18)	TS	IHC	capecitabine, fluorouracil
Taxanes (50)	TLE3	IHC	cabazitaxel, docetaxel

TARGETED THERAPY CLINICAL TRIALS (106)

Drug Class	Biomarker	Method	Investigational Agent(s)
Cell cycle inhibitors (4)	TP53	Next Gen SEQ	MK-1775
EGFR TKIs (79)	EGFR	Next Gen SEQ	CO-1686, HM61713, erlotinib, gefitinib
Pan-HER inhibitors (23)	EGFR	Next Gen SEQ	afatinib, dacomitinib, icotinib

( ) = 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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