



# Caris Molecular Intelligence® Associations List

The list below details the biomarkers assessed, technology platforms utilized and associated therapies or clinical trials. **Biomarkers and therapy associations may vary by the tumor type submitted.** The current and definitive list menu can be found online at [www.CarisMolecularIntelligence.com/profilemenu](http://www.CarisMolecularIntelligence.com/profilemenu).

*Individual assay results are always included with the final report.*

Agent	Biomarker	Platform	
afatinib <small>(assoc. in NSCLC only)</small>	EGFR	NGS Mutation	
	ERBB2 (Her2)	NGS Mutation	
afatinib + cetuximab <small>(combination assoc. in NSCLC only)</small>	EGFR T790M	NGS Mutation	
alectinib, ceritinib	ALK	IHC; NGS Fusion Analysis (RNA)	
aspirin <small>(assoc. in CRC only)</small>	PIK3CA	NGS Mutation	
atezolizumab <small>(assoc. in NSCLC only)</small>	PD-L1	IHC	
cabozantinib	RET	NGS Fusion Analysis (RNA)	
capecitabine, fluorouracil, pemetrexed	TS	IHC	
carboplatin, cisplatin, oxaliplatin	ATM	NGS Mutation	
	BRCA1 <sup>1</sup>	NGS Mutation	
	BRCA2 <sup>1</sup>	NGS Mutation	
	ERCC1	IHC	
cetuximab, panitumumab <sup>2</sup> <small>(assoc. in CRC only)</small>	BRAF	NGS Mutation	
	KRAS	NGS Mutation	
	NRAS	NGS Mutation	
	PIK3CA	NGS Mutation	
cetuximab	PTEN	IHC	
	EGFR	NGS CNV	
	crizotinib	ALK	IHC; NGS Mutation (DNA) & Fusion Analysis (RNA)
		cMET	NGS Mutation, CNV (DNA)
ROS1		NGS Fusion Analysis (RNA)	
dabrafenib, vemurafenib <sup>2</sup>	BRAF	NGS Mutation	
dacarbazine, temozolomide	MGMT	IHC	
	MGMT-Methylation	Pyrosequencing	
	IDH1 <small>(assoc. in High Grade Glioma only)</small>	NGS	
docetaxel, paclitaxel, nab-paclitaxel	TUBB3	IHC	
doxorubicin, liposomal-doxorubicin, epirubicin	TOP2A	IHC	
		CISH	
enzalutamide, bicalutamide	AR <small>(assoc. in TNBC only)</small>	IHC	
erlotinib, gefitinib <small>(assoc. in NSCLC only)</small>	EGFR	NGS Mutation	
	KRAS	NGS Mutation	
	PIK3CA	NGS Mutation	
	cMET	NGS CNV (DNA)	
	PTEN	IHC	

**IHC:** Immunohistochemistry **CISH:** Chromogenic *in situ* Hybridization **FA:** Fragment Analysis  
**NGS:** Next-Generation Sequencing **CNV:** Copy Number Variation by NGS **FUS:** Fusion Analysis by NGS

*Note: Biomarkers listed above may also be assessed for clinical trial opportunities and may include clinical trials associations.*

<sup>1</sup> May not be available for Medicare patients. Medicare reimburses BRCA1-2 for breast and ovarian cases only.

<sup>2</sup> In CRC, cetuximab/panitumumab, vemurafenib/dabrafenib, and trametinib may be reported in combination.

<sup>3</sup> Hormone therapies may include: tamoxifen, toremifene, fulvestrant, letrozole, anastrozole, exemestane, megestrol acetate, leuprolide, goserelin, bicalutamide, flutamide, abiraterone, enzalutamide, triptorelin, abarelix, degarelix.

Agent	Biomarker	Platform
everolimus, temsirolimus	ER <small>(assoc. in Breast only)</small>	IHC
	PIK3CA <small>(excluding CRC)</small>	NGS Mutation
exemestane + everolimus, fulvestrant, pabociclib combination therapy	ER	IHC
	ESR1	NGS Mutation
gemcitabine	RRM1	IHC
hormone therapies <sup>3</sup>	AR	IHC
	ER	IHC
	PR	IHC
imatinib	cKIT	NGS Mutation
	PDGFRA	NGS Mutation
irinotecan	TOPO1	IHC
topotecan <small>(excluding Breast, CRC, NSCLC)</small>		
lapatinib, pertuzumab, T-DM1	Her2/Neu	NGS CNV (DNA)
mitomycin-c	BRCA1 <sup>1</sup>	NGS Mutation
	BRCA2 <sup>1</sup>	
nivolumab, pembrolizumab <small>(assoc. in Bladder, Kidney, Melanoma, NSCLC only)</small>	PD-L1	IHC
	MSI <small>(pembrolizumab only)</small>	FA
olaparib	ATM <small>(assoc. in Prostate only)</small>	NGS Mutation
	BRCA1 <sup>1</sup>	
	BRCA2 <sup>1</sup>	
osimertinib <small>(assoc. in NSCLC only)</small>	EGFR T790M	NGS Mutation
palbociclib <small>(assoc. in Breast only)</small>	ER	IHC
	Her2/Neu	IHC
sunitinib <small>(assoc. in GIST only)</small>	cKIT	NGS
trametinib <sup>2</sup> <small>(assoc. in Melanoma only)</small>	BRAF	NGS
trastuzumab	ERBB2 (Her2) <small>(assoc. in NSCLC only)</small>	NGS
	Her2/Neu	IHC; NGS CNV (DNA)
	PTEN <small>(assoc. in Breast only)</small>	IHC
	PIK3CA <small>(assoc. in Breast only)</small>	NGS Mutation
vandetanib	RET	NGS Mutation (DNA) & Fusion Analysis (RNA)

# Biomarker Analysis by Tumor Type

The information below details the biomarkers analyzed by technology for the tumor type submitted. Before ordering testing services, please refer to the profile menu online ([www.CarisMolecularIntelligence.com/profilemenu](http://www.CarisMolecularIntelligence.com/profilemenu)) to view the most up-to-date listing of biomarkers that will be performed. Tests may vary if insufficient tumor samples are submitted.

MI Profile™			
Tumor Type	Immunohistochemistry (IHC)	Next-Generation Sequencing (NGS) <small>(see reverse for gene list)</small>	Other
Bladder	ERCC1, PD-L1, RRM1, TOP2A, TRKA/B/C (NTRK), TS, TUBB3	Mutation, CNV Analysis (DNA)	
Breast	AR, ER, ERCC1, Her2/Neu, PD-L1, PR, PTEN, TOPO1, TRKA/B/C (NTRK), TS	Mutation, CNV Analysis (DNA)	TOP2A <i>(Chromogenic in situ Hybridization)</i>
Cancer of Unknown Primary	ERCC1, PD-L1, RRM1, TOPO1, TRKA/B/C (NTRK), TS, TUBB3	Mutation, CNV Analysis (DNA)	
Cervix	ER, ERCC1, PD-L1, PR, RRM1, TOP2A, TOPO1, TRKA/B/C (NTRK), TS, TUBB3	Mutation, CNV Analysis (DNA)	
Cholangiocarcinoma/ Hepatobiliary	ERCC1, Her2/Neu, PD-L1, RRM1, TOPO1, TRKA/B/C (NTRK), TS, TUBB3	Mutation, CNV Analysis (DNA)	
Colorectal	ERCC1, MLH1, MSH2, MSH6, PD-L1, PMS2, PTEN, TOPO1, TRKA/B/C (NTRK), TS	Mutation, CNV Analysis (DNA)	MSI <sup>1</sup> <i>(Fragment Analysis)</i>
Endometrial	ER, ERCC1, MLH1, MSH2, MSH6, PMS2, PR, PD-L1, PTEN, RRM1, TOP2A, TOPO1, TRKA/B/C (NTRK), TS, TUBB3	Mutation, CNV Analysis (DNA)	MSI <sup>1</sup> <i>(Fragment Analysis)</i>
Gastric	ERCC1, Her2/Neu, PD-L1, TOP2A, TOPO1, TRKA/B/C (NTRK), TS, TUBB3	Mutation, CNV Analysis (DNA)	
GIST	PD-L1, PTEN, TRKA/B/C (NTRK)	Mutation, CNV Analysis (DNA)	
Glioma	ERCC1, PD-L1, TOPO1	Mutation, CNV (DNA); Fusion Analysis (RNA)	MGMT Methylation <i>(Pyrosequencing)</i>
Head & Neck	ERCC1, PD-L1, RRM1, TRKA/B/C (NTRK), TS, TUBB3	Mutation, CNV Analysis (DNA)	
Kidney	ERCC1, PD-L1, RRM1, TOP2A, TRKA/B/C (NTRK), TUBB3	Mutation, CNV Analysis (DNA)	
Melanoma	ERCC1, MGMT, PD-L1, TRKA/B/C (NTRK), TUBB3	Mutation, CNV Analysis (DNA)	
Neuroendocrine/ Small Cell Lung	ERCC1, PD-L1, MGMT, TOP2A, TS	Mutation, CNV Analysis (DNA)	
Non-Small Cell Lung	ALK, ERCC1, PD-L1, PTEN, RRM1, TOPO1, TRKA/B/C (NTRK), TS, TUBB3	Mutation, CNV (DNA); Fusion Analysis (RNA)	
Ovarian	ER, ERCC1, PD-L1, PR, RRM1, TOP2A, TOPO1, TRKA/B/C (NTRK), TUBB3	Mutation, CNV Analysis (DNA)	
Pancreatic	ERCC1, MLH1, MSH2, MSH6, PD-L1, PMS2, RRM1, TOPO1, TRKA/B/C (NTRK), TS, TUBB3	Mutation, CNV Analysis (DNA)	
Prostate	AR, ERCC1, PD-L1, TRKA/B/C (NTRK), TUBB3	Mutation, CNV Analysis (DNA)	
Sarcoma	ERCC1, MGMT, PD-L1, RRM1, TOP2A, TOPO1, TRKA/B/C (NTRK), TUBB3	Mutation, CNV Analysis (DNA)	
Thyroid	ERCC1, PD-L1, TOP2A, TRKA/B/C (NTRK)	Mutation, CNV Analysis (DNA)	
Other Tumors	ERCC1, PD-L1, RRM1, TOP2A, TRKA/B/C (NTRK), TS, TUBB3	Mutation, CNV Analysis (DNA)	

In certain instances, some biomarkers included in MI Profile or genes ordered individually will not associate with commercially available cancer therapies or clinical trials. For PD-L1 IHC testing, Dako antibody 22c3 is available upon request.

<sup>1</sup> If MSI is ordered and the tumor percentage is 20-49% or MSI testing is not possible, MMR IHCs (MLH1, MSH2, MSH6, PMS2) will be performed.