CARIS MI®
MOLECULAR INTELLIGENCE

Identify Tumor Origin and Inform Improved Treatment Decisions with MI GPSai™

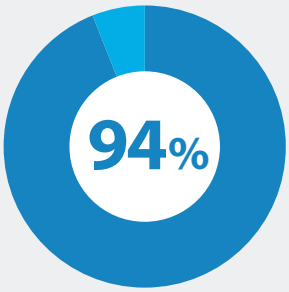
Typically, a Cancer of Unknown Primary (CUP) diagnosis is treated empirically and has very poor outcomes, with median overall survival less than one year[1]. MI GPSai™, a Genomic Prevalence Score, uses whole exome (DNA) sequencing and whole transcriptome (RNA) sequencing coupled with machine learning to aid in identifying the tissue of origin.

MI GPSai™

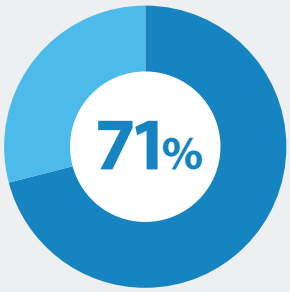
MI GPSai analyzes genomic and transcriptomic data to match a tumor's molecular signature across 21 cancer types from the Caris database. MI GPSai is intended to provide additional insight to help oncologists better manage cancers of unknown primary (CUP) or cases with atypical clinical presentation or clinical ambiguity.

MI GPSai Data

The MI GPSai algorithm was trained on genomic data from 34,352 cases and genomic and transcriptomic data from 23,137 cases, and was validated on an independent data set of 19,555 cases[2]. Study results showed:



MI GPSai predicted the tumor type in the labeled data set with an accuracy of over 94% on 93% of cases.



MI GPSai renders a prediction on 71% of CUP cases with consistent performance across all ranges of tumor purity.

Summary of performance in the prospective validation cohort:

Category	*n*	Above Threshold	Call Rate (%)	Sensitivity in Top 1(%)	Sensitivity in Top 2(%)	Sensitivity in Top 3(%)	Sensitivity in Top 4(%)	Sensitivity in Top 5(%)	Rule Outs/ Case	Rule Out Accuracy (%)
Global	13,661	12,699	93	94.7	97.2	97.9	98.1	98.2	17.6	99.9
Primary Specimen	7,521	7,087	94.2	96.1	98.2	98.7	98.8	98.9	17.8	100
Metastatic Specimen	5,942	5,426	91.3	93	96	97	97.2	97.4	17.4	99.9
Percent Tumor < 20, ≤ 50	4	3	75	100	100	100	100	100	18.7	100
Percent Tumor ≥ 20, ≤ 50	8,227	7,636	92.8	94.5	97	97.8	97.9	98	17.4	99.9
Percent Tumor > 50, ≤ 80	5,189	4,835	93.2	95	97.7	98.2	98.4	98.5	17.9	100
Percent Tumor > 80	241	225	93.4	96	96.4	96.4	96.4	96.9	18	99.9

MI GPSai is not available in New York.

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MI GPSai – Finding Misdiagnosed Patients

Considering that rates of inaccurate diagnosis ranges between 3% – 9%[3], MI GPSai provides an additional integral part of quality control and could lead to improved diagnostic accuracy.

Comprehensive tumor profiling with Caris Molecular Intelligence® performed with MI GPSai provides a comprehensive workup.

- Ability to identify misdiagnosed patients.
- Pathology proactively contacts treating oncologists to discuss discordant results to optimize patient care.

MI GPSai can be added to any solid tumor order by selecting the appropriate box on the Caris requisition at no additional cost or added specimen requirements. Results for MI GPSai will appear in the final Caris report. These results provide additional insight by assessing how closely the tumors match the genomic and transcriptomic signatures of cancer types to help you make more informed treatment decisions.

Example Caris Report: GPS (Genomic Prevalence Score)

Cancer Category	Prevalence
Lung Adenocarcinoma	93 %
Squamous Cell Carcinoma	5 %
Gastroesophageal Adenocarcinoma	1 %
Breast Adenocarcinoma	<1 %
Cholangiocarcinoma	<1 %
Pancreas Adenocarcinoma	<1 %
Central Nervous System Cancer	0 %
Cervical Adenocarcinoma	0 %
Colon Adenocarcinoma	0 %
GIST	0 %

For example purposes only, does not show complete list of MI GPSai cancer categories.

1. Massard C, Loriot Y, Fizazi K. Carcinomas of an unknown primary origin--diagnosis and treatment. Nat Rev Clin Oncol. 2011 Nov 1;8(12):701-10. doi: 10.1038/nrclinonc.2011.158. PMID: 22048624
2. Abraham, J., Spetzler, D., et al. (2021) Machine learning analysis using 77,044 genomic and transcriptomic profiles to accurately predict tumor type. *Translational Oncology,* 14(3) 101016. https://doi.org/10.1016/j.tranon.2021.101016
3. Peck, M., Moffat, D., Latham, B., Badrick, T., Review of diagnostic error in anatomical pathology and the role and value of second opinions in error preventions, J. Clin. Pathol. 71 (11) (2018) 995-1000.

To order or learn more, visit **www.CarisMolecularIntelligence.com.**
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