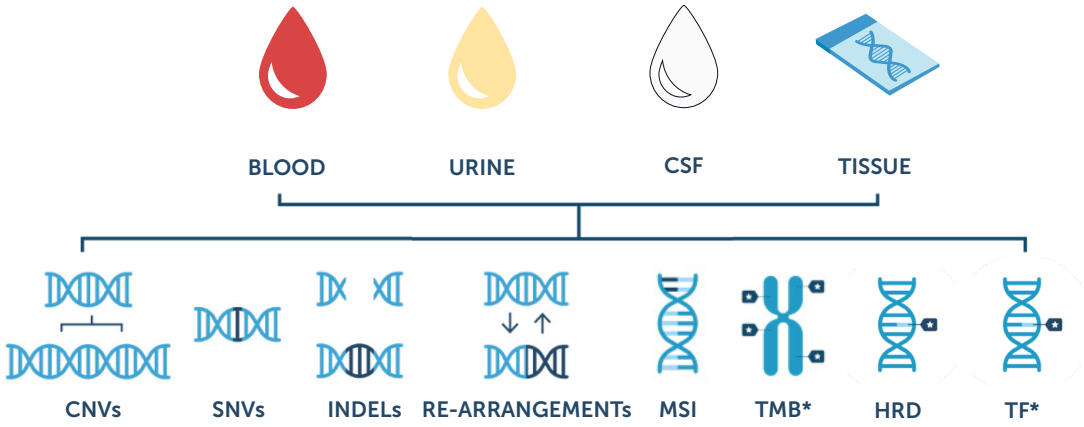
PredicineCARE™

Pan-Cancer CGP NGS Assay



140+
CLINICALLY RELEVANT ONCOLOGY BIOMARKERS

9+
CHEMOTHERAPY RESPONSE BIOMARKERS

Note: some features are only included in the RUO version. Additional information available upon request.

Performance Highlights

1 ng

Works with blood, urine, and CSF from as little as 1 ng of cfDNA

0.001% VAF

Reports down to 0.05% VAF (single timepoint) and 0.001% VAF (longitudinal)

200 genes

Covers comprehensive targets for CDx development (FDA BDD + PMA in process)

Assay Specifications

Feature	Blood/Plasma	Urine	Tissue
Sensitivity*	LoD: 0.25% VAF Reportable: 0.05% VAF (single)/ 0.001% VAF (longitudinal)	LoD: 0.3% VAF Reportable: 0.1% VAF	LoD: 2.5% VAF Reportable: 1% VAF
Specimen Type & Requirement	Blood (CLIA): 20 mL Blood (RUO): 4-10 mL Plasma (RUO): 2-5 mL	Urine: 25-40 mL	Tissue: ≥ $1mm^3$ (5-10 FFPE slides)
Turnaround Time (TAT)	≥ 6 business days	≥ 6 business days	[c] 10 business days
Target Sequence Coverage	20,000x	20,000x	2,000x
Sequencing	Illumina NGS		

* SNV-specific performance is shown. Full details available upon request

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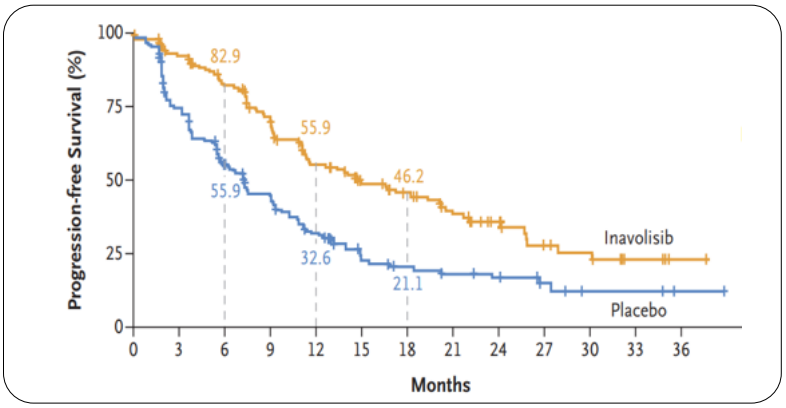
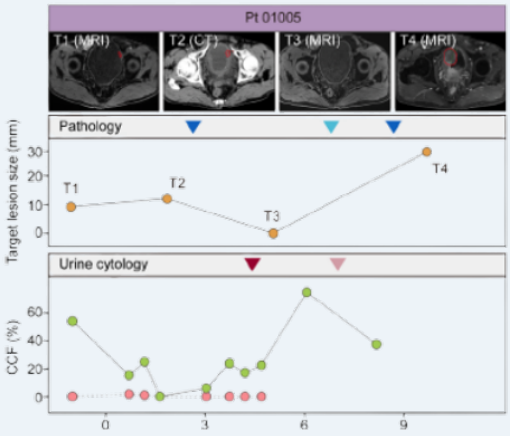
Blood-based patient enrollment

PredicineCARE supported blood-based enrollment in a Phase 3 PIK3CA-mutated breast cancer trial, leading to dual FDA/NMPA approvals and two NEJM articles.[1,2]



Urine-based molecular dynamics in MIBC



PredicineCARE enabled non-invasive residual disease and treatment monitoring during ADC-based combination therapy, with dynamic concordant with clinical outcomes.[3]

Global CDx development

PredicineCARE features FDA Breakthrough Device Designation (BDD) and ongoing CDx programs, supported by a globally harmonized testing platform.

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