PredicineATLAS™

600-Gene CLIA-certified cfDNA Liquid Biopsy Panel

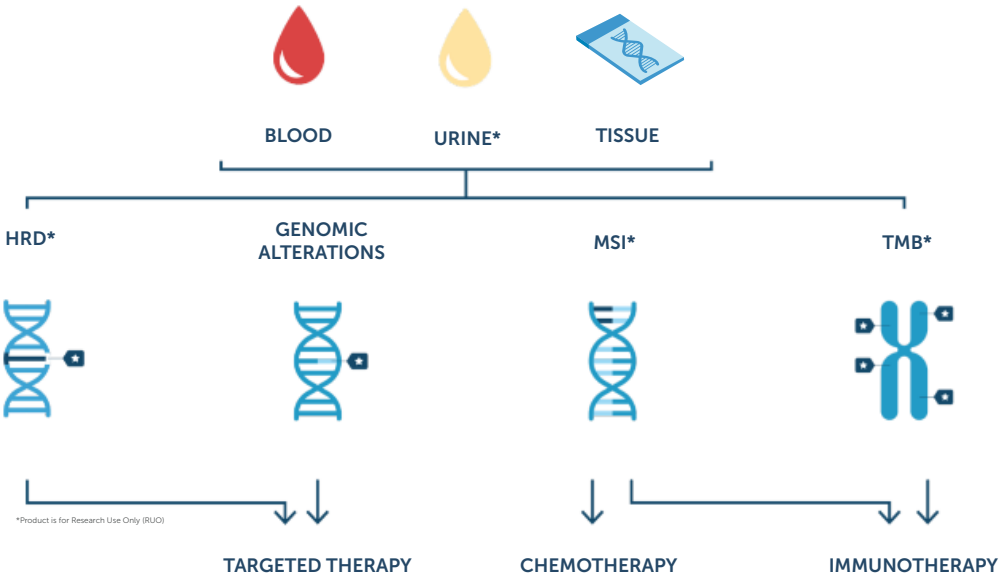
Pan-cancer liquid biopsy assay for comprehensive variant profiling

600

Key cancer genes interrogated

80+

Clinically relevant oncology biomarkers



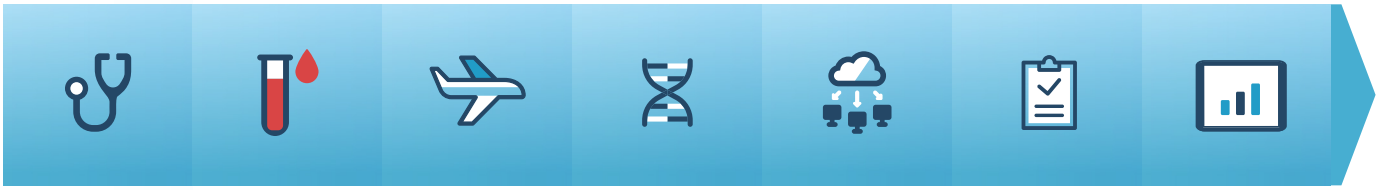
Methods and Reporting

- Identifies four main classes of genomic alterations (single-nucleotide variants, insertions and deletions, copy number variations including copy number reductions, and fusions)
- Covers genes of interest across drug development pipelines from targeted therapies to immunotherapies including Tumor Mutational Burden (TMB) and Microsatellite Instability MSI

	PredicineATLAS™
Size of Gene Panel	600
Mutation Types	SNV, Indel, CNA/CNR, Fusion
Target Enrichment	Hybrid Capture
Input cfDNA	5-30ng

https://doi.org/10.1371/journal.pone.0266889.t001

Workflow



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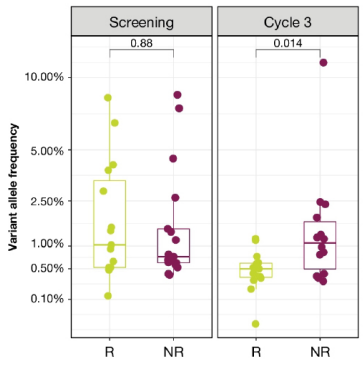
Performance Specifications

	Reportable Range	Allele Frequency/Copy Number	Sensitivity	Positive Predictive Value (PPV)
Single Nucleotide Variations	≥0.05%	≥0.5% AF	100%	100%
		0.25% - 0.5% AF	98.6%	99.2%
		<0.25% AF	78.3%	97.9%
Indels	≥0.05%	≥0.5% AF	100%	100%
		0.25% - 0.5% AF	98.6%	100%
		<0.25% AF	80%	100%
Re-arrangement	≥0.05%	≥0.5% AF	100%	100%
		0.375 - 0.5% AF	96.7%	100%
		0.25% - 0.375% AF	90%	100%
		<0.25% AF	33.3%	100%
Copy Number Gain	≥2.18	≥2.375 copies	100%	100%
		2.23 - 2.375 copies	100%	100%
		<2.23 copies	45%	81.8%
Copy Number Reductions	≤1.85	≤1.75 copies	100%	100%
		1.75 - 1.80 copies	93.6%	91.7%
		≤1.85 copies	66%	88.6%
Regions Analyzed	600 genes			
Panel Size	2.4 MB			
Sequencing and Bioinformatics	Illumina NGS			
Assay Sensitivity	0.25% report down to 0.05%			
Specimen Type and Requirement		CLIA	Research Use Only (RUO)	
	Liquid biopsy	8ml plasma 2 tubes of whole blood	2 ml plasma 1 tubes of whole blood 40ml urine	
	Tissue biopsy	10 FFPE slides	10 FFPE slides	
Target Sequence Coverage	>20,000x for biofluid, >2,000x for tissue			

Conclusions: Potential Clinical Utility in Real-World Patient Populations



- In clinical studies, PredicineATLAS™ demonstrated potential clinical utility in longitudinal assessment of cfDNA across multiple solid tumors to identify patients responding to therapeutics.
- The data here demonstrates a deep reduction in variant allele frequency (VAF) among responders to immune checkpoint inhibitor therapy in biliary tract cancer[1].

DY Oh, *et al.* Gemcitabine and cisplatin plus durvalumab with or without tremelimumab in chemotherapy-naive patients with advanced biliary tract cancer: an open-label, single-centre, phase 2 study Lancet Gastroenterol. Hepatol. 2022; 7: 522-532.