

# PredicineATLAS™

600-Gene CLIA Validated NGS Assay

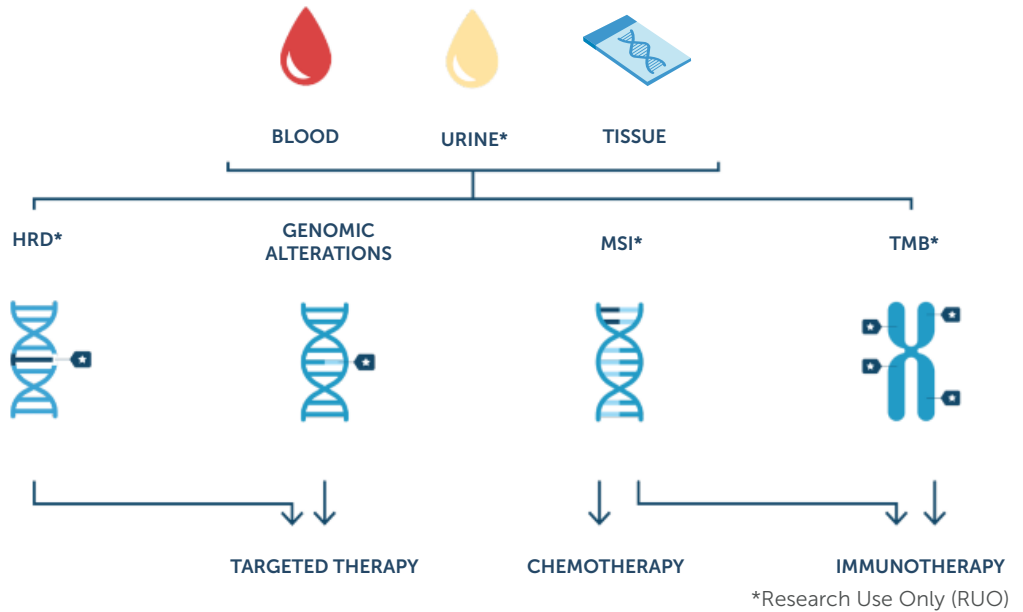
Pan-cancer NGS assay for comprehensive variant profiling compatible with liquid biopsy and solid tumor sample types

600

Key cancer genes interrogated

80+

Clinically relevant oncology biomarkers

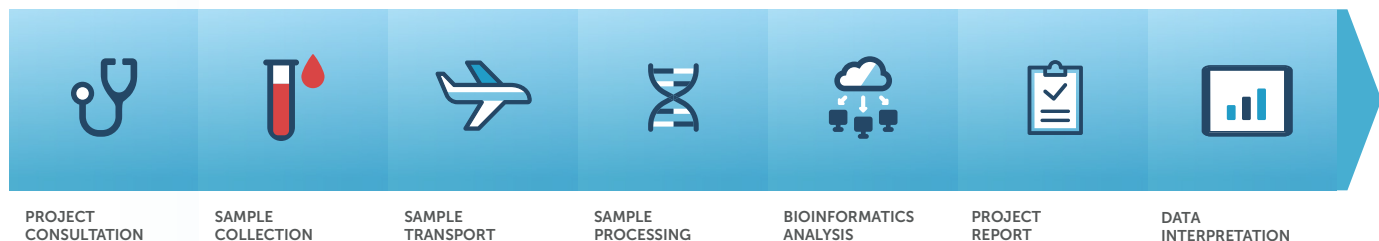


## Methods and Reporting

- Identifies four main classes of genomic alterations (single-nucleotide variants, insertions and deletions, copy number variations and DNA re-arrangement)
- Covers genes of interest across drug development pipelines from targeted therapies to immunotherapies including Tumor Mutational Burden (TMB), Microsatellite Instability (MSI) and Homologous Recombination Deficiency (HRD) for RUO testing

	PredicineATLAS™
Size of Gene Panel	600
Mutation Types	SNV, Indel, CNV & DNA re-arrangement
Target Enrichment	Hybrid Capture
Input cfDNA	5-30ng

## Workflow



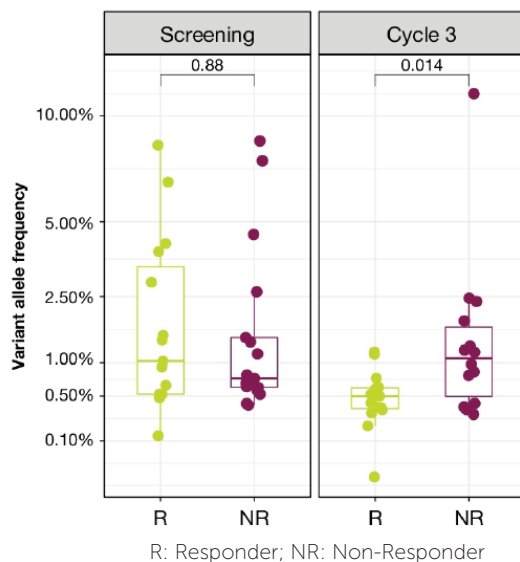
# Performance Specifications

Variant Type	Reportable Range	Allele Frequency/Copy Number	Sensitivity	Positive Predictive Value (PPV)
Single Nucleotide Variations	≥0.1%	>0.375% AF	100%	100%
		0.25% AF	97.5%	99.2%
		0.1% AF	30.0%	90%
Indels	≥0.05%	>0.375% AF	100%	100%
		0.25% AF	98.3%	100%
		0.1% AF	46.7%	100%
DNA Re-arrangement	≥0.05%	>0.375% AF	100%	100%
		0.25% AF	96.7%	100%
		0.1% AF	46.7%	100%
Copy Number Gain	≥2.18	ERBB2 > 2.37 copies	100%	100%
		MET and MYC > 2.23 copies	100%	100%
Copy Number Loss	≤1.85	≤1.75 copies	100%	100%
		1.75 - 1.80 copies	93.6%	91.7%
		1.80 - 1.85 copies	66%	88.6%
Regions Analyzed	600 genes			
Panel Size	2.4 MB			
Sequencing and Bioinformatics	Illumina NGS			
Specimen Type and Requirement	Liquid biopsy	<b>CLIA</b>	<b>RUO</b>	
		8 ml plasma 2 tubes of whole blood	2 ml plasma 1 tube of whole blood 40ml urine	
	Tissue biopsy	10 FFPE slides, with >1mm <sup>3</sup> tissue	10 FFPE slides	
Target Sequence Coverage	20,000x for liquid biopsy, 2,000x for tissue			

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

## Potential Clinical Utility in Real-World Patient Populations

Figure 1



- In clinical studies, PredicineATLAS™ demonstrated potential clinical utility in longitudinal assessment of cfDNA across multiple solid tumors to identify patients responding to therapeutics.
- In biliary tract cancer patients treated with immune checkpoint inhibitors, the observed variant allele frequency (VAF) was reduced in Responders (R) compared to Non-Responders (NR). (Figure 1).

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