PredicineATLAS™

600-Gene CLIA-certified cfDNA Liquid Biopsy Panel

A pan-cancer liquid biopsy test for comprehensive variant profiling

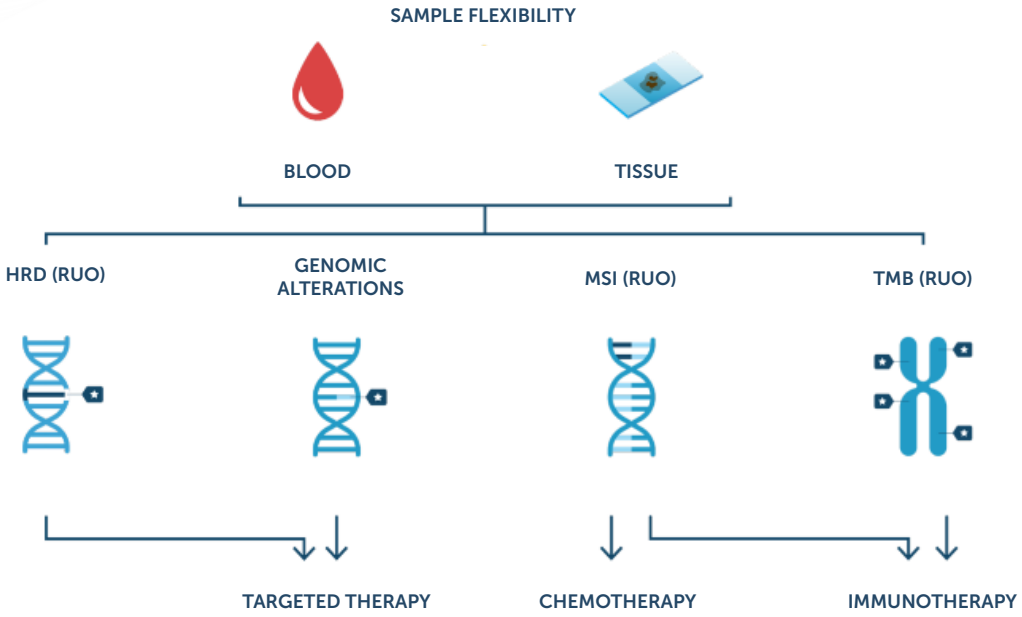
By the numbers

600

Key cancer genes evaluated

80+

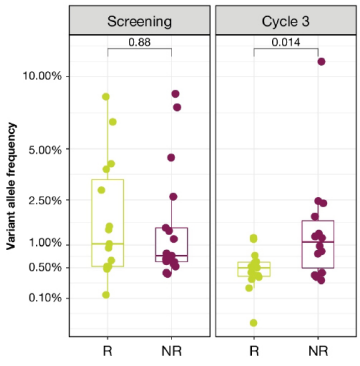
Tests for biomarkers linked to 80+ FDA Approved Oncology Therapies



Methods and Reporting

- Identifies four main classes of genomic alterations (base substitutions, insertions and deletions, copy number variations, and re-arrangements)
- Covers genes of interest across drug development pipeline from targeted therapies to immunotherapies
- Test results are provided in an interpretive report with clinically relevant genomic findings listed

Clinical Utility and Real-life Results



In clinical studies, PredicineATLAS showed high performance 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].

[1]Phase II study assessing tolerability, efficacy, and biomarkers for durvalumab (D) ± tremelimumab (T) and gemcitabine/cis-platin (GemCis) in chemo-naïve advanced biliary tract cancer (aBTC). Do-Youn Oh et al. Journal of Clinical Oncology 2020 38:15_suppl, 4520-4520

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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 Loss	≤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			

Sample Collection

1 Complete the Test Requisition Form (TRF).

2 Fill out barcode labels
- Patient ID/Initials
- DOB
- Collection Date

3 Collect blood as instructed on the collection instruction sheet included with the test kit. Place barcode label on each tube with barcode in the vertical position.

4 Place barcode label on the TRF, then fold and insert the TRF into the biohazard bag.

5 Place filled blood tubes into the foam tray.

6 Place filled foam tray into the specimen bag along with the TRF and zip seal the biohazard bag.

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