# PredicineATLAS™

## CLIA Validated 600-Gene NGS Assay

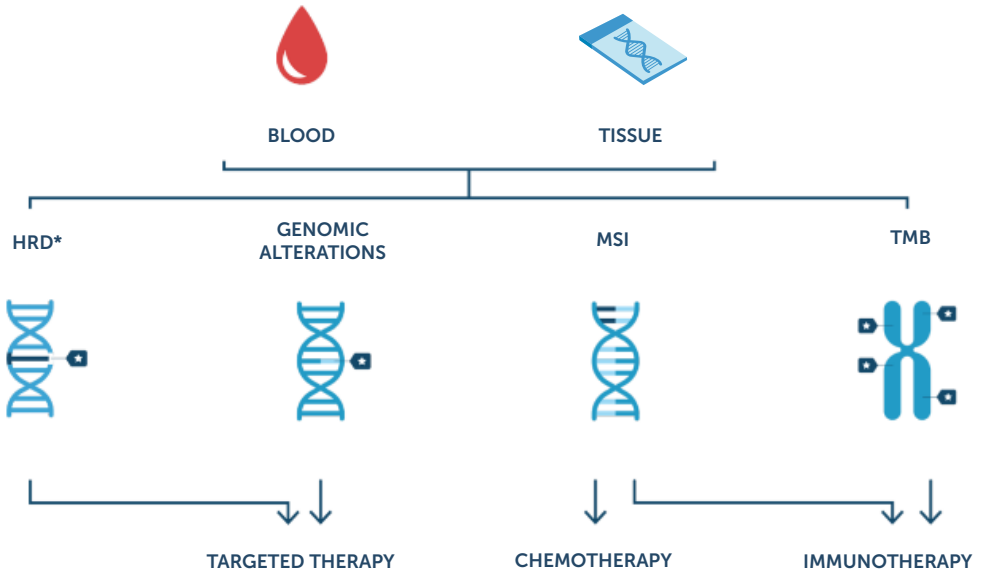
## Pan-cancer NGS assay for comprehensive variant profiling compatible with liquid biopsy and solid tumor sample types

**600**

Key cancer genes interrogated

**80+**

Clinically relevant oncology biomarkers



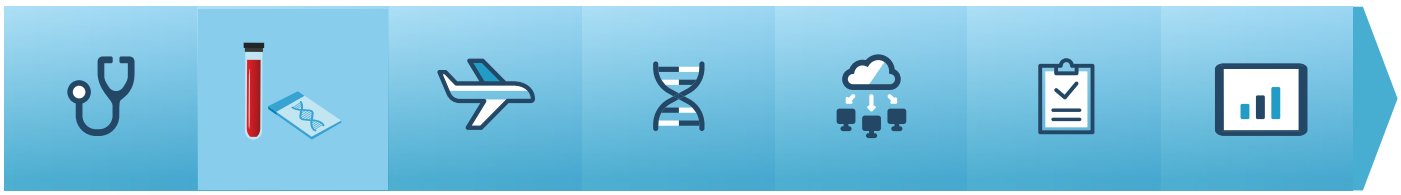

*Research Use Only (RUO)

## Methods and Reporting

- Identify key genetic characteristic of tumorous samples including, single-nucleotide variants, insertions and deletions, copy number variations, DNA re-arrangement, tumor mutational burden (TMB), and microsatellite instability (MSI)
- Covers genes of interest across drug development pipelines from targeted therapies to immunotherapies

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

## Workflow

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# Performance Specifications

| | Plasma | | | | Tissue | | | |
|---|---|---|---|---|---|---|---|---|
| Variant Type | Reportable Range | Allele Frequency/ Copy Number | Sensitivity | Positive Predictive Value (PPV) | Reportable Range | Allele Frequency/ Copy Number | Sensitivity | Positive Predictive Value (PPV) |
| Single Nucleotide Variations | ≥0.05% | 0.375% AF | 100% | 100% | ≥1% | 5% AF | 100% | 100% |
| | | 0.25% AF | 97.5% | 99.2% | | 3.5% AF | 100% | 100% |
| | | 0.1% AF | 30.0% | 90.0% | | 2.5% AF | 99.2% | 97.9% |
| Indels | ≥0.05% | 0.375% AF | 100% | 100% | ≥1% | 5% AF | 100% | 100% |
| | | 0.25% AF | 98.3% | 100% | | 3.5% AF | 100% | 100% |
| | | 0.1% AF | 46.7% | 100% | | 2.5% AF | 94.0% | 100% |
| DNA Re-arrangement | ≥0.05% | 0.375% AF | 100% | 100% | ≥1% | 3.5% AF | 100% | 100% |
| | | 0.25% AF | 96.7% | 100% | | | | |
| | | 0.1% AF | 46.7% | 100% | | | | |
| Copy Number Gain | ≥2.18 | 2.23-2.37 copies | 100% | 100% | ≥2.5 | 4.5-8.5 copies | 100% | 100% |
| Regions Analyzed | 600 genes | | | | | | | |
| Panel Size | 2.4 MB | | | | | | | |
| Sequencing | Illumina NGS | | | | | | | |
| TAT | 6 days - Plasma | | | | 10 days - Tissue | | | |
| Specimen Type and Requirement | | CLIA | RUO | | | CLIA | RUO | |
| | Liquid biopsy | 20 mL blood | 2-5 mL plasma<br>4-10 mL blood | | Tissue biopsy | ≥ 1mm³ tissue (5-10 FFPE slides) | ≥ 1mm³ tissue (5-10 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.

| Biomarker [Plasma Sample] | Tumor Fraction | Sensitivity | Positive Predictive Value (PPV) |
|---|---|---|---|
| Microsatellite Instability (MSI) | 20% TF | 100% | 100% |
| | 10% TF | 100% | 100% |
| | 1% TF | 100% | 100% |
| | 0.7% TF | 60.0% | N/A |
| Tumor Mutational Burden (TMB) | 10% TF | 100% | 100% |
| | 1% TF | 100% | 100% |
| | 0.7% TF | 100% | 100% |
| | 0.5% TF | 50.0% | N/A |

# Clinical Utility in Real-World Patient Populations

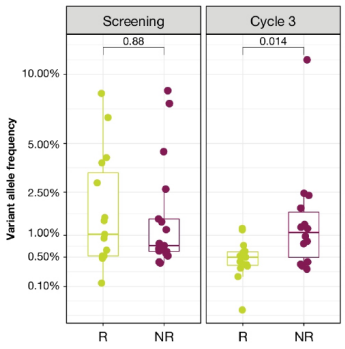


Figure 1 R: Responder; NR: Non-Responder

- 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-naive patients with advanced biliary tract cancer: an open-label, single-centre, phase 2 study Lancet Gastroenterol. Hepatol. 2022; 7: 522-532