Liquid Biopsy NGS Testing Panel

Cell-free DNA/RNA Assay for Disease Diagnosis and Monitoring

Test Information

Targeted next-generation sequencing (NGS) of clinically relevant genes using cell-free DNA (cfDNA) and RNA (cfRNA) isolated from plasma. This system allows for the evaluation of multiple biomarkers using a highly sensitive workflow capable of detecting single nucleotide variants (SNVs) and insertions and deletions (indels) in plasma cfDNA to a level of 0.1% allele fraction.

NGS workflow: Cell-free DNA and RNA are isolated from the plasma fraction of whole blood samples. The purified nucleic acids are subjected to a series of reactions to prepare the nucleic acids in preparation for next-generation sequencing. This process generates multiple copies of each gene region of interest which are tagged with unique identifiers to sample and molecular purity throughout analysis. This workflow is optimized and validated to generate highly accurate and reproducible results across the target panel.

Using a single tube of blood, our assay is designed for the analysis of single nucleotide variants, short indels, copy number variations and fusions that are frequently identified in cancer samples. The assay provides a highly sensitive approach for detecting alterations across all variant classes. Testing of cell-free plasma DNA/RNA from solid tumor diseases provides an alternative solution that doesn't require tissue specimens. This is now available for clinical use through a simple blood draw and routine shipping to our CLIA certified and CAP-accredited molecular laboratory.

Highlights

Covers all actionable markers supported by drug labels and clinical guidelines for hotspots, SNVs, indels, copy number variations (CNVs) and gene fusions

Relevant evidence for genes on the panel

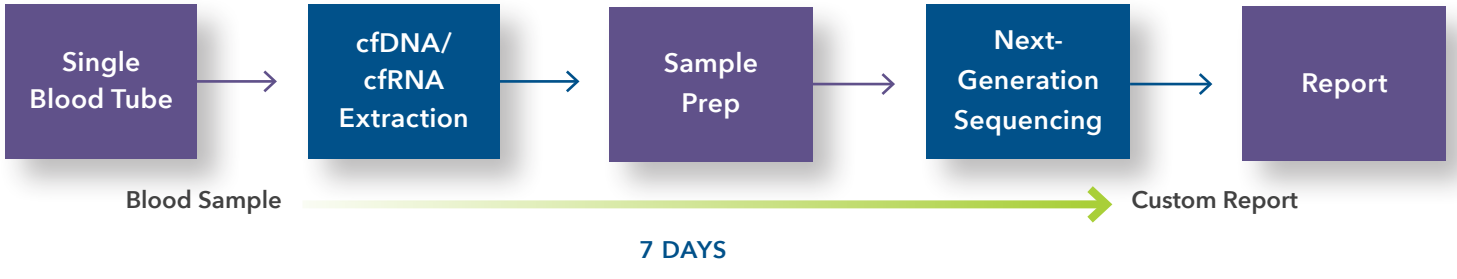
- Approved labels (FDA, EMA)
- Guidelines (ESMO)
- Clinical Trials (Global)
- May be used in absence of tissue

Reporting

Oncomine™ Knowledgebase Reporter

Clinical/Research Applications

- Targetable alterations before first-line NSCLC therapy
- Monitoring disease status and response to therapy
- May assist in the prediction of relapse



Target Information

Assay	Target	Unique Genes	DNA	RNA
Pan Cancer	cfDNA + cfRNA	52	50	12

Thermo Fisher Oncomine Pan-Cancer Liquid Biopsy Assay

Hotspot Genes		Tumor Suppressor Genes	Copy Number Genes	Gene Fusions
AKT1	HRAS	APC	CCND1	ALK
ALK	IDH1	FBXW7	CCND2	BRAF
AR	IDH2	PTEN	CCND3	ERG
ARAF	KIT	TP53	CDK4	ETV1
BRAF	KRAS		CDK6	FGFR1
CHEK2	MAP2K1		EGFR	FGFR2
CTNNB1	MAP2K2		ERBB2	FGFR3
DDR2	MET		FGFR1	MET
EGFR	MTOR		FGFR2	NTRK1
ERBB2	NRAS		FGFR3	NTRK3
ERBB3	NTRK1		MET	RET
ESR1	NTRK3		MYC	ROS1
FGFR1	PDGFRA			
FGFR2	PIK3CA			
FGFR3	RAF1			
FGFR4	RET			
FLT3	ROS1			
GNA11	SF3B1			
GNAQ	SMAD4			
GNAS	SMO			

Note: Testing is provided for profiling of solid tumor biomarkers only. Please do not submit samples from patients with hematological disorders.

Liquid Biopsy NGS Testing Specifications			
• 52 genes • Single library from DNA and RNA	• 272 amplicons • >900 hotspots, SNVs and indels	• Extended coverage of TP53 • 96 fusions	• 12 CNVs • MET exon 14 skipping

Ordering Information

Specimen requirements: Peripheral blood, 10ml Streck Cell Free DCT tube.

Storage and transportation: Ambient storage and transportation.
Ship same day as drawn whenever possible; specimens <24 hours old preferred.

Turnaround Time: 7 days from sample receipt to report.

NeoGenomics Laboratories is a specialized oncology reference laboratory providing the latest technologies, testing, partnership opportunities, and interactive education to the oncology and pathology communities. We offer the complete spectrum of diagnostic services in molecular testing, FISH, cytogenetics, flow cytometry, and immunohistochemistry through our nation-wide network of CAP-accredited, CLIA-certified laboratories.

Committed to research as the means to improve patient care, we provide Pharma Services for pharmaceutical companies, in vitro diagnostic manufacturers, and academic scientist-clinicians. We promote joint publications with our client physicians. NeoGenomics welcomes your inquiries for collaborations. Please contact us for more information.

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