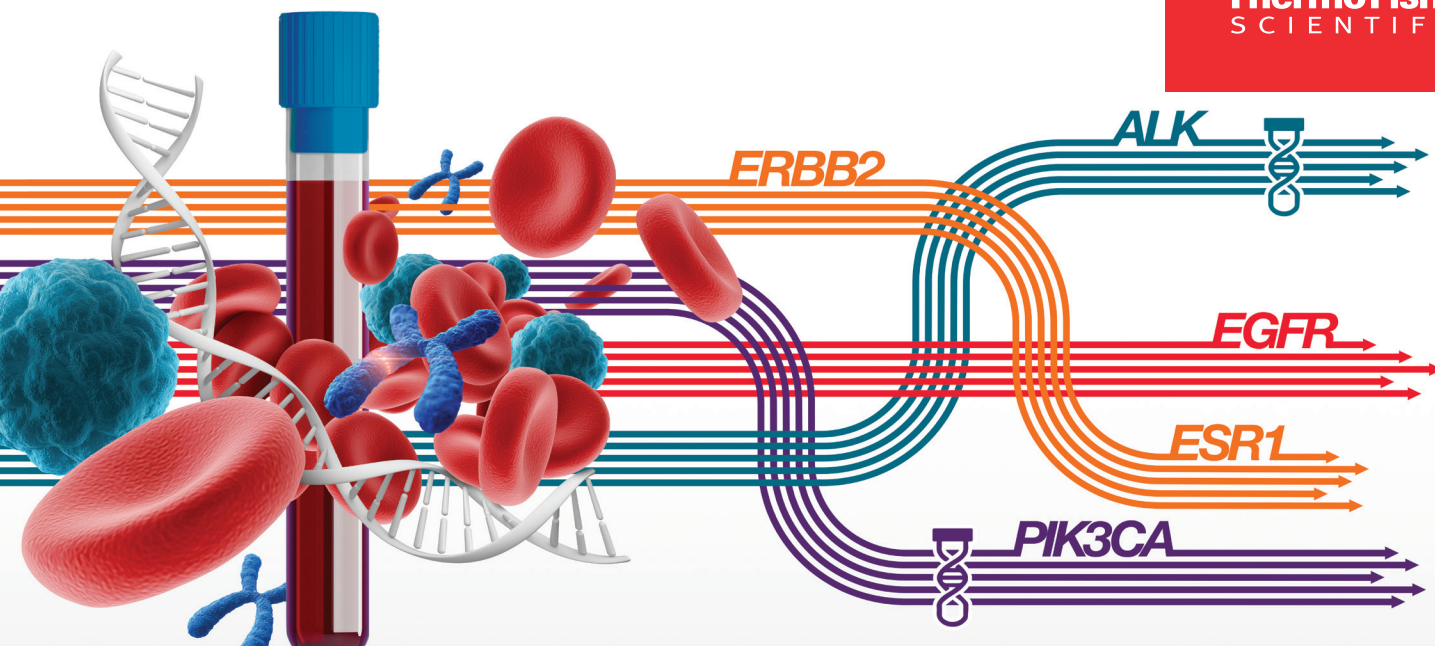




Pan-cancer liquid biopsy testing for clinical oncology research

The Oncomine™ Pan-Cancer Cell-Free Assay is a targeted next-generation sequencing (NGS) assay that allows insights in oncogenes associated with more than 18 different tumor types. Through simultaneous multibiomarker analysis of DNA and RNA from just one tube of blood, results are now only 2-3 days away.

- **Multiple biomarkers from one blood sample**—this complementary, noninvasive alternative to traditional tissue biopsies only requires one tube of blood for detection of important non-small cell lung cancer (NSCLC) biomarkers (SNVs, Indels, CNVs, and gene fusions)

- **One end-to-end workflow**—go from blood sample to variant report in 2-3 days
- **Reliable results from multiple sample sources**—such as ctDNA from blood, bile, cerebro-spinal fluid, and urine

Table 1. Gene list for Oncomine Pan-Cancer Cell-Free Assay.

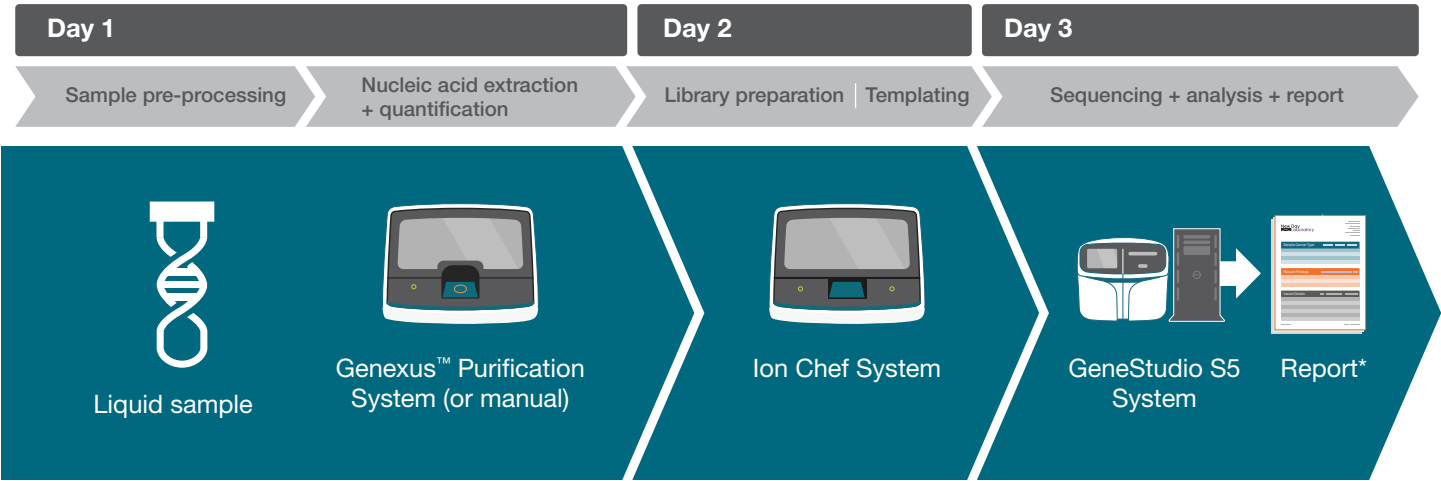
SNVs/Indels			CNVs	Fusions
AKT1	FGFR2	MTOR	CCND1	ALK
ALK	FGFR3	NRAS	CCND2	BRAF
APC*	FGFR4	NTRK1	CCND3	ERG
AR	FLT3	NTRK3	CDK4	ETV1
ARAF	GNA11	PDGFRA	CDK6	FGFR1
BRAF	GNAQ	PIK3CA	EGFR	FGFR2
CHEK2	GNAS	PTEN*	ERBB2	FGFR3
CTNNB1	HRAS	RAF1	FGFR1	MET
DDR2	IDH1	RET	FGFR2	NTRK1
EGFR	IDH2	ROS1	FGFR3	NTRK3
ERBB2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

* Full-length gene

Table 2. 18 tumor types included in Oncomine Pan-Cancer Cell-Free Assay.

Tumor types		Top 10 genes ranked by mutation frequency
	Bladder	<i>TP53, PIK3CA, FGFR3, HRAS, ERBB2, KRAS, CTNNB1, BRAF, NRAS, FBXW7</i>
	Brain and CNS	<i>TP53, IDH1, PIK3CA, EGFR, CHEK2, ALK, CTNNB1, BRAF, PTEN, PDGFRA</i>
	Breast	<i>PIK3CA, TP53, ERBB2, PTEN, SF3B1, AKT1, ERBB3, ESR1, KRAS, FGFR2</i>
	Cervical	<i>PIK3CA, FBXW7, TP53, KRAS, ERBB2, PTEN, ERBB3, MTOR, CTNNB1, SMAD4</i>
	Colorectal	<i>PIK3CA, FBXW7, TP53, KRAS, ERBB2, PTEN, ERBB3, MTOR, CTNNB1, SMAD4</i>
	Endometrial	<i>PIK3CA, TP53, CTNNB1, PTEN, KRAS, FGFR2, FBXW7, MTOR, NRAS, ERBB2</i>
	Esophageal	<i>TP53, PIK3CA, SMAD4, FBXW7, KRAS, ERBB2, APC, CTNNB1, PTEN, SMO</i>
	Gastric	<i>TP53, PIK3CA, KRAS, FBXW7, ERBB3, ERBB2, SMAD4, CTNNB1, APC, MAP2K1</i>
	Head and neck	<i>TP53, PIK3CA, HRAS, PTEN, FBXW7, RET, KRAS, FGFR3, BRAF, ERBB2</i>
	Kidney	<i>TP53, MTOR, CHEK2, PIK3CA, PTEN, MET, FGFR3, EGFR, KRAS, SF3B1</i>
	Liver	<i>CTNNB1, TP53, PIK3CA, KRAS, PTEN, KIT, IDH1, GNAS, APC, FGFR2</i>
	Lung	<i>TP53, KRAS, EGFR, PIK3CA, BRAF, NRAS, PTEN, FBXW7, APC, CTNNB1</i>
	Melanoma	<i>BRAF, NRAS, TP53, MAP2K1, CTNNB1, GNA11, PTEN, IDH1, KIT, GNAQ</i>
	Ovarian	<i>TP53, PIK3CA, KRAS, EGFR, CTNNB1, CHEK2, ERBB2, MET, FBXW7, NRAS</i>
	Pancreatic	<i>KRAS, TP53, SMAD4, APC, GNAS, CTNNB1, SF3B1, PIK3CA, BRAF, FGFR1</i>
	Prostate	<i>TP53, PIK3CA, CTNNB1, AR, CHEK2, APC, PTEN, IDH1, AKT1, BRAF</i>
	Sarcoma	<i>TP53, IDH1, NRAS, PIK3CA, KRAS, FGFR4, ERBB2, IDH2, HRAS, CTNNB1</i>
	Thyroid	<i>BRAF, NRAS, HRAS, RET, TP53, KRAS, PIK3CA, AKT1, GNAS, CCND1</i>

Figure 1. Next-generation sequencing (NGS) workflow—GeneStudio S5 System



*Reporting options include OncoPrint Reporter and other reporting solutions.

A comprehensive liquid biopsy NGS workflow for streamlined detection and analysis of variants from 52 oncogenes (Table 1) that are associated with 18 different cancer types (Table 2).



Your in-house NGS workflow

Optimized to support operational efficiency from sample to report, the NGS workflow for the Oncomine Pan-Cancer Cell-Free Assay consists of three key steps, enabling you to go from blood sample to report in 2-3 days. During sample preparation, cell-free nucleic acids are extracted, enriched,

and amplified from liquid samples, such as blood, bile, cerebro-spinal fluid, and urine. These amplicon-based libraries are then assembled overnight before targeted sequencing. Our integrated informatics solution then takes you from variant caller to a finished report that provides contextual insights about sample-specific variants.

Table 3. Performance data of the Oncomine Pan-Cancer Cell-Free Assay

Validation item	SNV/indel	CNV	Fusion
Analytical sensitivity	>99.9% at 0.5% allele fraction 80% at 0.1% allele fraction	>99% at >1.35 fold amplification	>99% at 0.4% fusion fraction
Analytical specificity	>99%	>99%	>99%
Analytical accuracy	>99%	>99%	>99%
Precision within run	98%	>99%	>99%
Precision across runs	99%	>99%	>99%
Tissue concordance	>99% for informative variants	>99% for informative variants	N/A

Thermo Fisher Scientific. (2020). Oncomine Pan-Cancer Assay White Paper.

Ordering information

Product	Cat. No.
Pan-cancer liquid biopsy solutions on Ion GeneStudio S5 System	
Oncomine Pan-Cancer Cell-Free Assay	A37664
Tag Sequencing Barcode Set 1-24	A31830
Tag Sequencing Barcode Set 25-48	A31847
Ion GeneStudio S5 Prime System	A38196
Ion GeneStudio S5 Plus System	A38195
Ion GeneStudio S5 System	A38194
Ion 550 Chip Kit	A34538
Ion 540 Chip Kit	A27766
Ion 530 Chip Kit	A27764
Ion Chef System	4484177
Ion 550 Kit-Chef	A34541
Ion 540 Kit-Chef	A30011
Ion 510 & Ion 520 & Ion 530 Kit-Chef	A34461
Oncomine informatics	
Ion Reporter Server System	4487118

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