



OncoMine cfDNA assays

The Ion Torrent™ OncoMine™ cfDNA assays are multibiomarker next-generation sequencing (NGS) assays that enable detection of primary driver and resistance mutations from cell-free DNA (cfDNA) down to a level of 0.1%.

- **Single tube of blood**—the end-to-end two-day workflow is enabled from NGS
- **Low limit of detection**—variant detection down to 0.1%, with high sensitivity and specificity for single nucleotide variant (SNV) hotspots and indels
- **High-value content**—including hotspots identified by the OncoNetwork consortium and other clinical researchers around the world
- **Sample tolerance**—flexible input amounts as low as 1 ng, and tolerance of sample input variability to accommodate more of your samples
- **Cost effective**—uniform coverage of tumor type-specific amplicons enables optimization of samples per sequencing run
- **Optimized analysis**—the variant caller has been optimized to increase sensitivity and specificity, providing information on mutation percentage

The OncoMine cfDNA assays have been developed together with the OncoNetwork Consortia.

Genes	Selected SNV hotspots
OncoMine™ Lung cfDNA Assay	
<i>ALK, BRAF, EGFR, ERBB2, KRAS, MAP2K1, MET, NRAS, PIK3CA, ROS1, and TP53</i>	<i>EGFR</i> : T790M, C797S, L858R, Exon 19 del
	<i>KRAS</i> : G12X, G13X, Q61X
	<i>BRAF</i> : V600E
	<i>ALK</i> : 1151Tins, L1152R, C1156Y, F1174C, L1196M
	<i>PIK3CA</i> : E545K, H1047R, E542K
OncoMine™ Breast cfDNA Assay	
<i>AKT1, EGFR, ERBB2, ERBB3, ESR1, FBXW7, KRAS, PIK3CA, SF3B1, and TP53</i>	<i>PIK3CA</i> : E545K, H1047R
	<i>AKT1</i> : E17K
	<i>ESR1</i> : mutations associated with anti-estrogen resistance
	<i>TP53</i> : mutations associated with loss of function
	<i>ERBB2</i> : mutations associated with sensitivity to anti- <i>ERBB2</i> therapies
OncoMine™ Colon cfDNA Assay	
<i>AKT1, BRAF, CTNNB1, EGFR, ERBB2, FBXW7, GNAS, KRAS, MAP2K1, NRAS, PIK3CA, SMAD4, TP53, and APC</i>	<i>KRAS/NRAS</i> : G12/G13/Q61
	<i>BRAF</i> : V600E
	<i>PIK3CA</i> : E545K, H1047R
	<i>TP53</i> : R175H, R273H/C/L
	Recurrent deleterious <i>APC</i> mutations (including p.R876*, p.R1114*, p.Q1378*, p.R1450*)
	<i>SMAD4</i> : R361C/H
	<i>CTNNB1</i> : S45F, T41A

“Using the OncoMine Lung cfDNA Assay, we were able to amplify more difficult samples. The assay allowed us the detection of mutations like *EGFR* T790M down to 0.14% allelic fraction.”

— José Luis Costa, PhD, Senior Researcher, Institute of Molecular Pathology and Immunology of the University of Porto, Portugal

The Oncomine cfDNA assays and the Ion S5™ Systems enable tumor heterogeneity and reoccurrence research studies from minimal input DNA (Figure 1).

When combined with the Ion S5™ XL System, the Oncomine cfDNA assays are part of a highly accurate, reproducible workflow from blood sample to variant data in two days.

The Oncomine™ Lung cfDNA Assay achieves high correlation between variants called in formalin-fixed, paraffin-embedded (FFPE) samples and those called in cfDNA from plasma of late-stage lung cancer samples (Table 1).

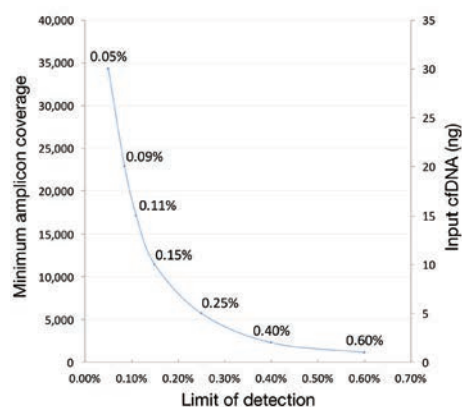


Figure 1. Amplicon coverage and input material determine limit of detection using the Oncomine cfDNA assays.

Table 1. Mutation Correlation between FFPE and cfDNA samples.

Samples	Variant	FFPE	cfDNA
Late-stage lung cancer clinical research samples			
1	<i>EGFR</i> -L858R	71.42%	2.62%
2	<i>TP53</i> -R158L	51.89%	4.32%
3	<i>MET</i> -T1010I <i>KRAS</i> -G12C	43.87% 34.62%	51.75% 0.28%
4	NA	No detection	No detection
5	<i>EGFR</i> -L858R <i>MET</i> -T1010I <i>TP53</i> -Y220C	58.44% 41.93% 35.54%	7.28% 48.72% 1.93%
6	<i>TP53</i> -R158L	10.19%	1.26%

Bold—somatic mutations
Normal font face—germline mutations

Ordering information

Product	Cat. No.
Oncomine Lung cfDNA Assay	A31149
Oncomine Breast cfDNA Assay	A31183
Oncomine Colon cfDNA Assay	A31182
Tag Sequencing Barcode Set 1–24	A31830
Tag Sequencing Barcode Set 25–48	A31847
Applied Biosystems™ MagMAX™ Cell-Free DNA Isolation Kit	A29319

The Oncomine cfDNA assays are enabled on the Ion S5 XL System, Ion S5 System, Ion Proton™ System, and Ion PGM™ System.

Find out more at thermofisher.com/cfDNA-assays

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