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Comprehensive and simultaneous genomic profiling

The Oncomine Comprehensive Assay Plus for broad pan-cancer profiling across multiple biomarkers and cancer tissue types

Designed for the detection of known and novel biomarkers associated with targeted and immuno-oncology therapies, this new solution for the testing of solid tumor samples covers over 500 genes associated with a variety of tumor types, offering myriad potential pan-cancer research implications.

The Ion Torrent™ Oncomine™ Comprehensive Assay Plus enables simultaneous analysis of both DNA and RNA in a single workflow, and fits seamlessly into existing workflows for Ion Chef™ and Ion GeneStudio™ S5 systems, providing relevant variant data from integrated informatics.

Key features of the Oncomine Comprehensive Assay Plus include:

- Over 500 unique genes, including driver genes across solid tumors
- Comprehensive and simultaneous genomic profiling (from DNA and RNA) for research of key targeted and immunotherapy biomarkers
- All classes of variants: SNVs, indels, **CNVs**, fusions, and splice variants
- Immuno-oncology content: microsatellite instability (MSI) and tumor mutational burden (TMB)
- **Sensitive** targeted fusion **detection**
- **Low sample input** (tested with sample inputs down to 1 ng of DNA/RNA or a single slide)
- **Very low QNS**, enabling up to 99% sequencing success [1, 2]
- Fully integrated analysis and reporting
- Fast turnaround time, driven by an automated workflow that enables you to go from sample to report in days

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The Oncomine Comprehensive Assay Plus is part of Oncomine™ Solutions, a growing menu of assays designed for the way you work. With options ranging from a small, specialized two-gene assay for *BRCA* to a large >500 gene assay for multibiomarker profiling across multiple cancer types, Oncomine Solutions can help you choose the best solution for your specific oncology research needs.

Streamlined NGS workflow

Oncomine informatics

Our streamlined Ion Torrent™ Oncomine™ informatics workflow is an integrated, internally developed sample-to-report solution for data analysis that takes you from initial sequence analysis of many variants through annotation of relevant biomarkers associated with cancer drivers to a final report that is fully customizable and can be translated into multiple languages. A sample report from the Oncomine Comprehensive Assay Plus workflow is at right.

References

1. Anna-Lena Volckmar, Jonas Leichsenring, Martina Kirchner et al. (2019) Combined targeted DNA and RNA sequencing of advanced NSCLC in routine molecular diagnostics: Analysis of the first 3,000 Heidelberg cases. *Int J Cancer*. https://doi.org/10.1002/ijc.32133.
2. Chih-Jian Lih, Robin D. Harrington, David J. Sims et al. (2017) Analytical validation of the next-generation sequencing assay for a nationwide signal-finding clinical trial. *J Mol Diagn* 19(2):313-327. https://doi.org/10.1016/j.jmoldx.2016.10.007.

Oncomine Comprehensive Assay Plus: Assay performance

A

Assay performance on reference control (Thermo Scientific™ AcroMetrix™ Oncology Hotspot Control)					
Variant type	**TP**	**FP**	**FN**	**Sensitivity**	**PPV**
SNV	2,181	4	33	98.51%	99.82%
Indel	62	2	1	98.41%	96.88%

B

Assay performance on CNV					
Variant type	**TP**	**FN**	**TN**	**Sensitivity**	**Specificity**
CNV gain	34	1	12	97.1%	100%
CNV loss	17	2	12	89.4%	

Figure 1. Distributions of total and amplicon-mapped DNA reads (A) show excellent on-target rates across 243 FFPE samples from a diverse set of tissue types. A high proportion of amplicon-assigned reads reflect high assay specificity in target amplification. A median of ~35 million reads per sample provide >2,400 average read depth. Reads were distributed across amplicons with >95% uniformity and at least 500x base coverage for >95% of the targets **(B)** to ensure detection of variants with low allele frequency (>5%).

Oncomine Comprehensive Assay Plus: TMB performance

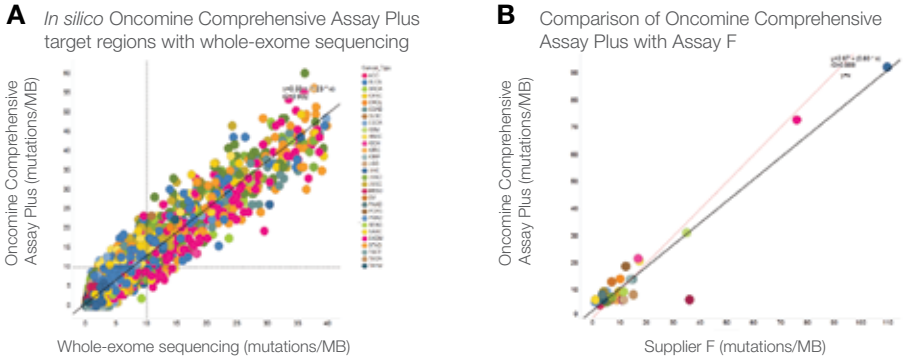

Figure 2. TMB performance of Oncomine Comprehensive Assay Plus. Whole-exome sequencing (WES) is viewed as the gold standard for TMB quantitation. *In silico* analysis against WES was performed to characterize the TMB performance of the Oncomine Comprehensive Assay Plus. **(A)** A scatter plot shows high correlation between the targeted assay (y-axis) and WES (x-axis) mutation counts, which was downloaded from TCGA MC3[3]. **(B)** A second comparison was conducted against a commercially available assay with real-world samples, and also shows high correlation in TMB determination.

Find out more at **thermofisher.com/ocaplus**

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