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Comprehensive genomic profiling without compromises

The Oncomine Comprehensive Assay Plus enables pan-cancer genomic profiling across multiple biomarkers with high testing success

Designed for the detection of known and novel biomarkers associated with research of targeted therapies and immunotherapies, the Ion Torrent™ Oncomine™ Comprehensive Assay Plus is the most comprehensive of all the Ion Torrent™ Oncomine™ assays.

Encompassing over 500 genes, this pan-cancer solution 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 optimized bioinformatics.

Key features of the Oncomine Comprehensive Assay Plus include:

Comprehensive profiling—profile hundreds of genes simultaneously for relevant insights from somatic variants, key immuno-oncology (IO) biomarkers, and mutational signatures in one workflow, using a single assay

Somatic mutational analysis—detect all variant classes (SNVs, indels, CNVs, fusions, splice variants) and key IO biomarkers, and analyze mutational processes or signatures

Immuno-oncology applications—study potential response to immunotherapies with TMB assessment and determine predisposition to genetic hypermutability by comparing MSI regions

Low input requirements—low FFPE sample inputs of 20 ng DNA or RNA is sufficient for profiling over 500 genes, with fewer failed results

High testing success—low quantity not sufficient (QNS) readings and high sequencing success rates of >95% means more samples are successfully tested [1,2]

Bioinformatics pipeline—streamlined bioinformatics analysis pipeline is optimized for the Oncomine Comprehensive Assay Plus and packaged in a user-friendly experience

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The Oncomine Comprehensive Assay Plus is part of Oncomine™ Solutions, a broad assay menu for all key oncology applications. With options ranging from a small, targeted two-gene assay for *BRCA* to a large >500 gene assay for comprehensive profiling across multiple cancer types, Oncomine Solutions offer end-to-end, clinical research–grade workflows that address specific challenges when implementing NGS for oncology research.

Streamlined NGS workflow

Oncomine informatics

The streamlined Ion Torrent™ Oncomine™ informatics workflow is an optimized, sample-to-report solution for data analysis that delivers consistent and accurate results. From initial sequence analysis through annotation of relevant biomarkers to creation of a clear and concise report, this complete workflow solution creates efficiencies and enables you to quickly filter to variants of interest and focus on the meaning of your data.

Oncomine Comprehensive Assay Plus: assay performance

A

Assay performance on reference control (Thermo Scientific™ AcroMetrix™ Oncology Hotspot Control)		
Variant type	**Sensitivity**	**Specificity**
SNV	98.9%	99.7%
Indel	100%	96.6%

B

Assay performance on CNV		
Variant type	**Sensitivity**	**Specificity**
CNV gain	100%	100%
CNV loss	100%	100%

Figure 1. The performance of the Oncomine Comprehensive Assay Plus has been verified using (A) commercially available standard material and (B) reference cell lines.

Oncomine Comprehensive Assay Plus: TMB assessment

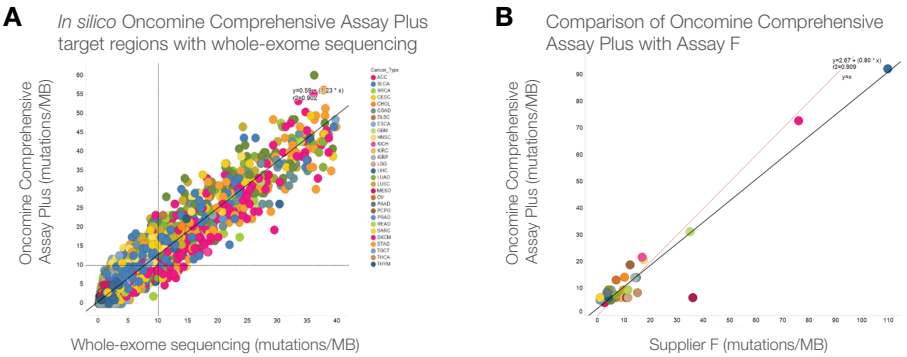

Figure 2. TMB assessment with the Oncomine Comprehensive Assay Plus. (A) Whole-exome sequencing (WES) is viewed as the gold standard for TMB quantitation. *In silico* analysis against WES was performed to characterize the TMB assessment of the Oncomine Comprehensive Assay Plus. A scatter plot shows high correlation between the targeted assay (y-axis) and WES (x-axis) mutation counts, which was downloaded from the Multi-Center Mutation Calling in Multiple Cancers project from The Cancer Genome Atlas. **(B)** Orthogonal TMB vs. observed Oncomine Comprehensive Assay Plus TMB: a second comparison was conducted against a commercially available assay with FFPE samples, and also demonstrates high correlation in TMB values.

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.* 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. doi.org/10.1016/j.jmoldx.2016.10.007.

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