Oncomine Comprehensive Assay Plus

The all-in-one CGP research test from one vendor, with results in as little as 3 days

The Ion Torrent™ Oncomine™ Comprehensive Assay Plus, available on Ion GeneStudio™ S5 systems, offers a complete, end-to-end comprehensive genomic profiling (CGP) solution. The assay detects a broad range of genomic alterations including single-nucleotide variants (SNVs), insertions and deletions (indels), copy number variations (CNVs), and fusions from 517 genes.

Additionally, the assay detects genomic signatures such as homologous recombination deficiency (HRD), tumor mutational burden (TMB), and microsatellite instability (MSI). Leveraging proven Ion Torrent™ technology, the Oncomine Comprehensive Assay Plus delivers a complete, easy, fast, and robust solution to help you meet your laboratory research needs, even at varying levels of next-generation sequencing (NGS) expertise.

Oncomine Comprehensive Assay Plus features and benefits

Complete

One end-to-end vendor for sample-to-report solutions, including instruments, consumables, analysis, and support, simplifies implementation into your lab to help maximize efficiency

Easy

90% less hands-on time (HOT) compared to hybrid capture-based NGS assays can help reduce handling errors, free up precious time for your lab staff, and reduce labor costs [1]

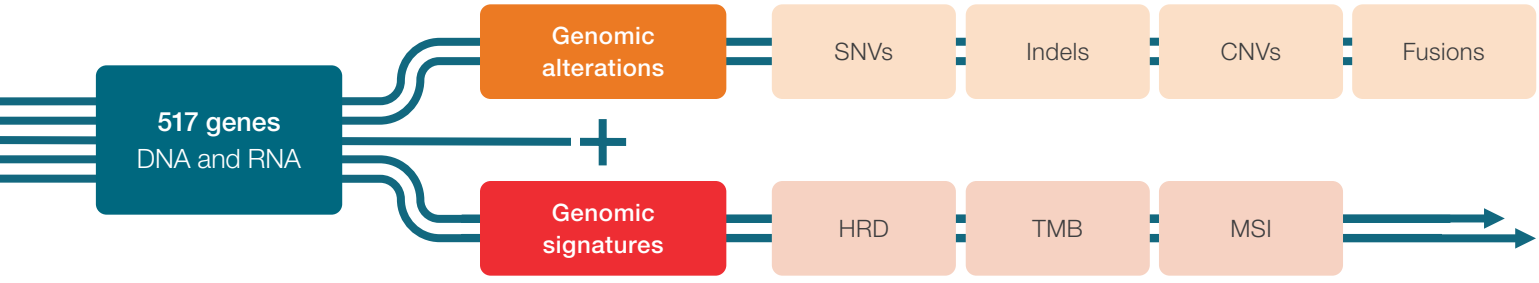
Fast

As little as a 3-day turnaround time (TAT) enabled by Ion Torrent technology and automated workflows means results are delivered in a timely manner to support critical decisions

Robust

~94% success rate with a minimal input requirement of just 20 ng of DNA or RNA allows for testing more samples, including those that are typically considered insufficient in quantity (QNS) for other technologies [2]

Comprehensive genomic profiling with the Oncomine Comprehensive Assay Plus



Oncomine Comprehensive Assay Plus performance

Accurate detection of a broad range of genomic alterations plus HRD, TMB, and MSI signatures

Detect a broad range of genomic alterations such as SNVs, indels, CNVs including large genomic rearrangements (LGRs), and fusions including splice variants with high sensitivity and specificity [4]. To help ensure breadth of fusion coverage, >1,300 isoforms are covered across 49 fusion driver genes. Sample input requirements of only 20 ng DNA/RNA are sufficient to simultaneously profile genomic alterations from 517 genes, plus genomic signatures like HRD, TMB, and MSI, to help maximize insights on the underlying oncogenic drivers.

Oncomine Comprehensive Assay Plus performance across genomic alterations [3]

Alteration	Sensitivity (%)	Specificity (%)
SNVs	99.6	97.6
Indels	99.5	98.1
CNV gain (CN>8)	97.6	99.9
CNV loss (homozygous)	86.7	99.9
Fusions	100	97.5

SNV/indel performance compared with Thermo Scientific™ AcroMetrix™ Oncology Hotspot Control. CNV performance evaluated with FFPE samples (n=82) compared to Applied Biosystems™ OncoScan™ CNV Assay. Fusion performance evaluated with FFPE samples (n=40) compared to orthogonal methods.

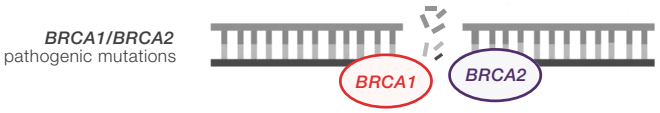
Measure both causes and consequences of HRD

This assay detects mutations in 47 genes associated with homologous recombination repair (HRR), including LGRs in *BRCA1* and *BRCA2*, which are known causes of HRD. In addition, the consequences of HRD or genomic scarring are measured using a genomic instability metric (GIM).

The GIM is a numeric value between 0 and 100 that summarizes the unbalanced copy number changes across the autosomes resulting from HRD. Higher GIM values correlate with more genomic instability.

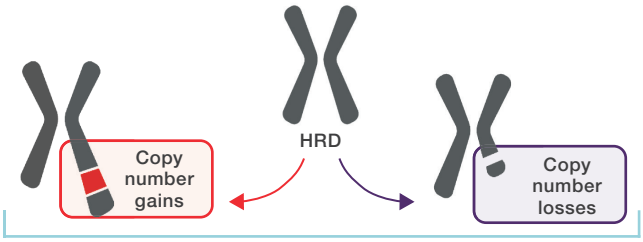
HRD assessment with the Oncomine Comprehensive Assay Plus

Homologous recombination repair genes



47 HRR genes: *ABRAXAS1, ATM, ATR, BAP1, BARD1, BLM, BRCA1, BRCA2, BRIP1, CDK12, CHEK1, CHEK2, FANCA, FANCC, FANCD2, FANCE, FANCF, FANCG, FANCI, FANCL, FANCM, MLH1, MRE11, NBN, PALB2, PARP1, PARP2, PARP3, POLD1, POLE, PPP2R2A, PTEN, RAD50, RAD51, RAD51B, RAD51C, RAD51D, RAD54L, RAD52, RNASEH2A, RNASEH2B, RNASEH2C, RPA1, SLX4, TP53, XRCC2, XRCC3*

Genomic instability metric



Genomic instability metric (GIM) is a proprietary measurement that quantifies genomic scarring with a value between 0 and 100

Oncomine Comprehensive Assay Plus HRD performance in ovarian cancer research samples

In a retrospective multicenter study of n=100 stage III–IV ovarian cancer research samples from the MITO16/MaNGO-OV2 clinical study, HRD status was determined based on the presence of pathogenic mutations in *BRCA1/BRCA2* in combination with GIM using a predefined threshold of ≥16 to define a high GIM [4].

The Oncomine Comprehensive Assay Plus had good overall concordance with various orthogonal methods for HRD assessment in ovarian cancer research samples.

Concordance of the Oncomine Comprehensive Assay Plus HRD status with reference in ovarian cancer research samples [4]

		Reference		
		Positive	Negative	Total
Oncomine Comprehensive Assay Plus	Positive	51	7	58
	Negative	1	27	28
	Total	52	34	86

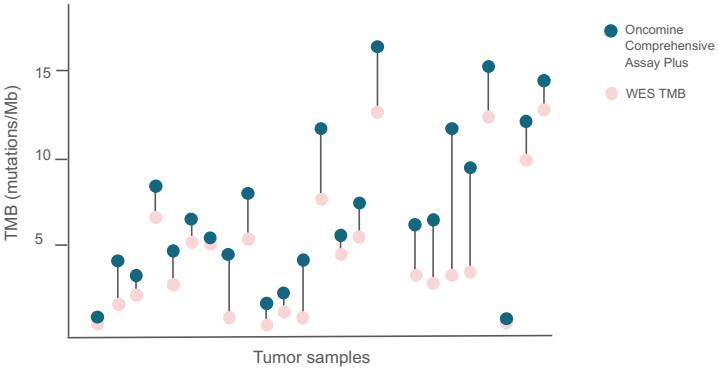
Sensitivity	98.1%
Specificity	79.4%
Overall concordance	90.7%

Measure TMB and MSI to advance immunotherapy biomarker research

The Oncomine Comprehensive Assay Plus evaluates TMB with >1 Mb of exonic coverage, resulting in a high correlation with whole-exome sequencing (WES) across tumor types. Accurate assessment of TMB (mutations/Mb) is important because studies have shown that a high TMB may correlate with response to immune checkpoint inhibitors.

The Oncomine Comprehensive Assay Plus determines MSI status by assessing 76 microsatellite markers with high sensitivity in different cancer types, especially in colorectal and gastric cancers. MSI is reported as a numeric score with high MSI scores considered as MSI-high, and low MSI scores considered as microsatellite stable (MSS).

Oncomine Comprehensive Assay Plus TMB comparison to WES [3]



Oncomine Comprehensive Assay Plus MSI comparison to PCR [3]

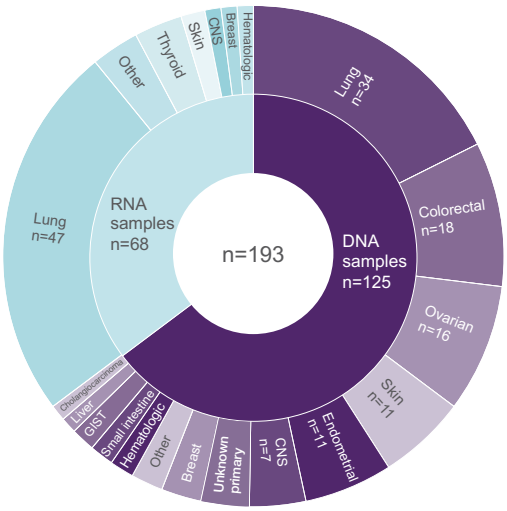
Cancer	Samples (n)	Sensitivity (%)	PPV (%)
Colorectal	198	98	100%
Gastric	36	100	100%
Endometrial	97	93	100%

Analytical performance of Oncomine Comprehensive Assay Plus in a multicenter study across tumor types

In a multicenter study across five different countries in Europe using the Oncomine Comprehensive Assay Plus and the Ion GeneStudio™ S5 Prime System, the overall sequencing success rate was ~94% using a cohort of 193 precharacterized pan-cancer tumor samples (DNA and RNA) [2].

The assay demonstrated high analytical performance as part of a sensitive and specific platform for molecular tumor profiling, including detection of complex genomic signatures [2].

FFPE tumor research samples used for the analytical evaluation of the Oncomine Comprehensive Assay Plus



Oncomine Comprehensive Assay Plus concordance to orthogonal methods in a multicenter research study [2]

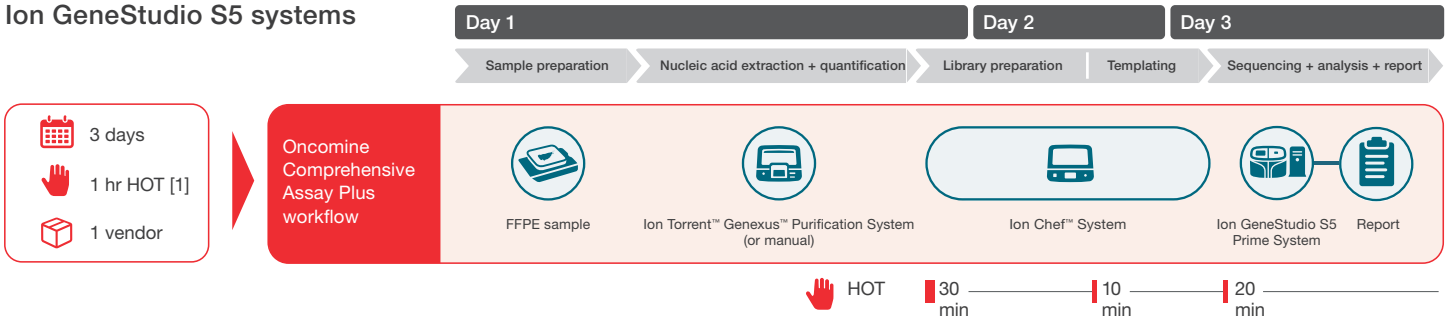
Alteration/signature	Samples (n)	Concordance (%)
SNVs	258	95.3
Indels	32	90.6
CNVs	57	96.5
Fusions	51	96.1
HRD	18	100
TMB	32	81.3
MSI (pan-cancer/ colorectal cancer)	26/10	80.8/100

Complete end-to-end CGP solution with results in as little as 3 days from 1 vendor

Leveraging proven Ion Torrent technology and highly automated systems that only require ~1 hour of HOT, CGP results can be reported in as little as 3 days. Further, a ~94% success rate with only 20 ng of DNA or RNA means that more samples can be tested, even challenging samples like cytological specimens [2].

As a single vendor of sample-to-report solutions, including instruments, consumables, analysis, and support, Thermo Fisher Scientific simplifies bringing in-house CGP to your lab at varying levels of NGS expertise.

Ion GeneStudio S5 systems



Bring the power of in-house CGP to your lab with Ion Chef and Ion GeneStudio S5 systems

The Oncomine Comprehensive Assay Plus can be run on the Ion GeneStudio S5 Prime System or the Ion GeneStudio™ S5 Plus System with the Ion 550™ chip. Ion GeneStudio S5 systems are easy to use and leverage the speed of semiconductor sequencing for high-quality sequencing data. When paired with the Ion Chef System for automated library preparation and templating, the NGS workflow can be further streamlined with minimal HOT.

Ordering information

Product	Quantity	Cat. No.
Oncomine Comprehensive Assay Plus, automated library preparation	32 samples	A49667
Oncomine Comprehensive Assay Plus RNA, automated library preparation	32 samples	A49671
Oncomine Comprehensive Assay Plus, manual library preparation	24 samples	A48577
Oncomine Comprehensive Assay Plus RNA, manual library preparation	24 samples	A48578

References

1. One hr hands-on time for the Oncomine Comprehensive Assay Plus for library prep and sequencing compared to competitor literature stating 10.5 hr needed for manual workflow—current as of August 2024.
2. Jantus-Lewintre, E., et al. (2023). Multicentric evaluation of amplicon-based next-generation sequencing solution for local comprehensive molecular tumor profiling. ESMO Poster 219P.
3. Internal R&D data.
4. Normanno, N. (2023). Future Clinical Perspective of HRD Testing in Ovarian Cancer Samples Using NGS CGP. Genome Web Webinar May 2023.

Learn more about the Oncomine Comprehensive Assay Plus at **thermofisher.com/oncomine-ocaplus**