A new world of NGS
A new day for precision oncology

Oncomine Solutions: an end-to-end workflow for clinical oncology research

For Research Use Only. Not for use in diagnostic procedures.

Find it at **fishersci.com**

fisher scientific
part of Thermo Fisher Scientific

Broad genomic profiling by NGS is the foundation for advancing precision oncology

It's time to bring NGS into your laboratory, and it has never been easier

Introducing the Ion Torrent™ Genexus™ System with a one-day, automated specimen-to-report workflow.*

- **One-day workflow**
- **Two user touchpoints**
- **10 minutes of hands-on time**

* Specimen-to-report workflow will be available after the Ion Torrent™ Genexus™ Purification System and integrated reporting capabilities are added in 2020.

Educational website

Learn more about precision oncology research, next-generation sequencing, and Oncomine™ Solutions at oncomine.com

- Learn about our comprehensive portfolio of products
- Hear from our customers
- Access on-demand webinars, infographics, and articles
- Subscribe to get the news first
- Follow our blog to read what we and our customers think about hot topics

Jose Luis Costa,

Clinical Researcher at the Ipatimup Center and Affiliated Professor at the Department of Pathology, University of Porto Faculty of Medicine, Portugal, was an early tester of the Genexus System. He says:

"The instrument is extremely intuitive. I would say that it is simple enough for a child to use. Anyone–even without any expertise–can just plug in the instrument and start working with it. It tells you exactly what to do, step by step. You don't really need to prepare in advance to work with it. In fact, the only thing you need is one pipette."

Philip Jermann,

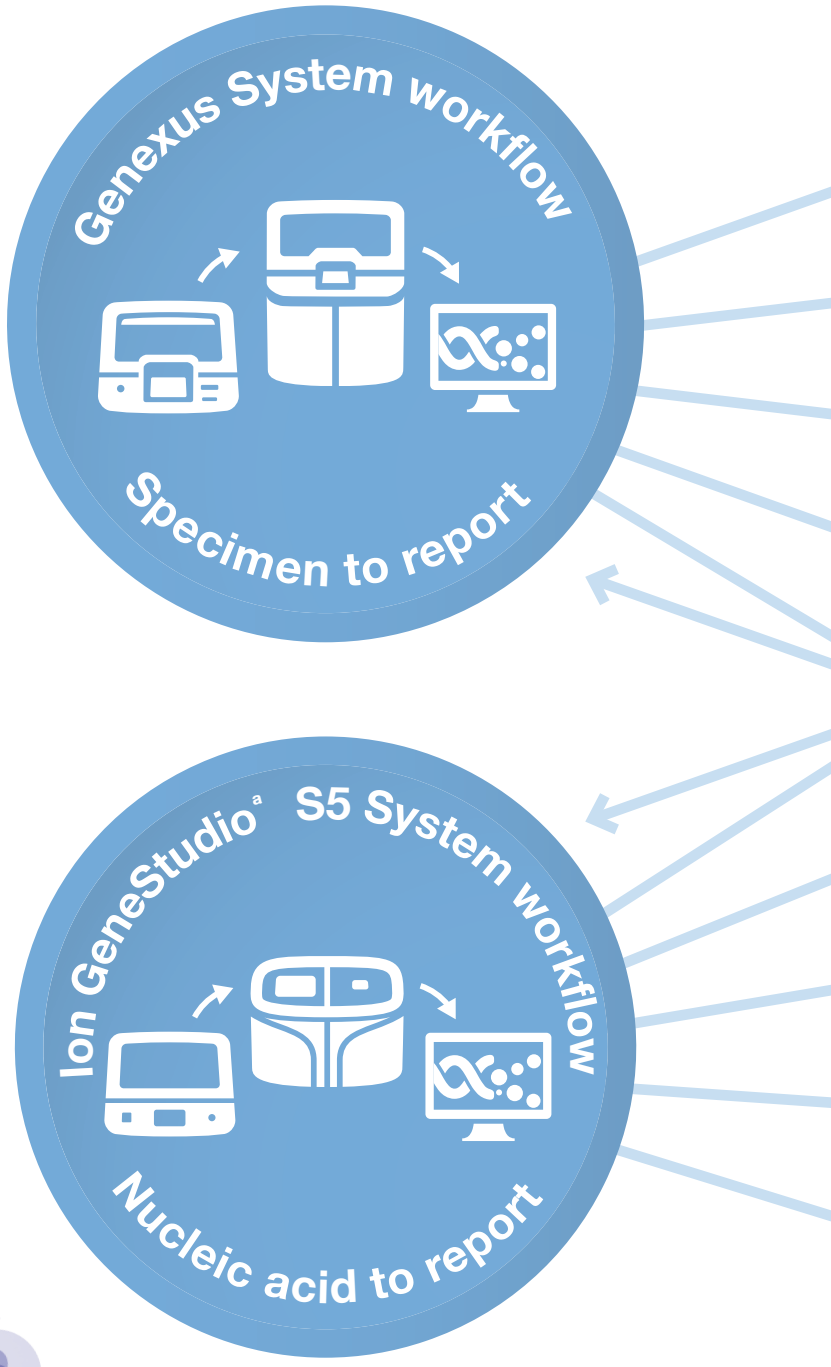
Head of Molecular Assay Development Unit of the Institute of Medical Genetics and Pathology, University Hospital Basel, was an early tester of the Genexus System. He says:

"The Ion Torrent Genexus System is based on technology that has evolved over the last 10 years. I was an early adopter, so I have followed its entire development. The method, to the best of my knowledge, has been cited in more than 6,000 scientific papers. Recently, a seminal retrospective study from the University of Heidelberg in Germany that used the Ion Torrent technology demonstrated a nearly 97 percent sequencing success rate across more than 3,000 non-small cell lung cancer samples, and a rejection rate, mostly due to quantity-not-sufficient errors, of only around 3 percent."

Retrieved from "What is the real impact" in *The Pathologist,* December 2019

Oncomine Solutions

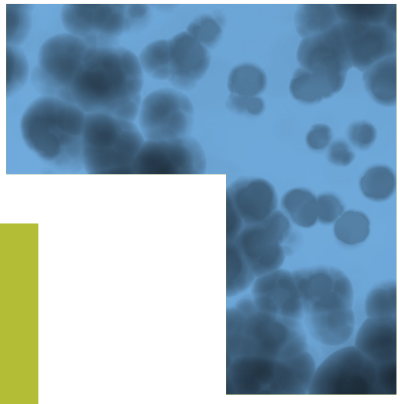
Oncomine™ Solutions offer end-to-end workflows that address specific challenges when implementing next-generation sequencing (NGS) for clinical oncology research. We understand that NGS applications and content need to be tailored for your lab's needs. That's why we offer two types of workflows, a broad assay portfolio, complete bioinformatics, and technical support, to suit the way you work.




Key genes for one-day genomic profiling
Minimum sample input requirement
Oncomine™ Reporter software
Specialized implementation support
End-to-end protocols tested on clinical research samples
Broad assay menu across key applications

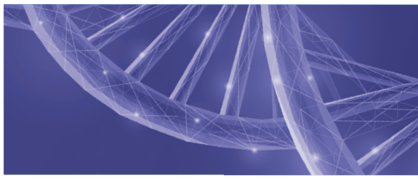
One size does not fit all

Oncomine Solutions give you options, because each individual, sample, and lab is unique



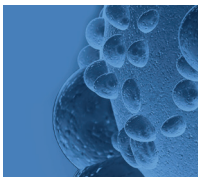
Heme-oncology research solutions

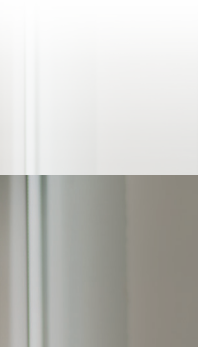
- New: Ion Torrent™ Oncomine™ BCR IGH-LR Assay and Oncomine™ BCR IGH-SR Assay
- New: Ion Torrent™ Oncomine™ Lymphoma Assay
- Coming soon: Ion Torrent™ Oncomine™ Myeloid MRD Assay
- Ion Torrent™ Oncomine™ Childhood Cancer Research Assay
- Ion Torrent™ Oncomine™ Myeloid Research Assay

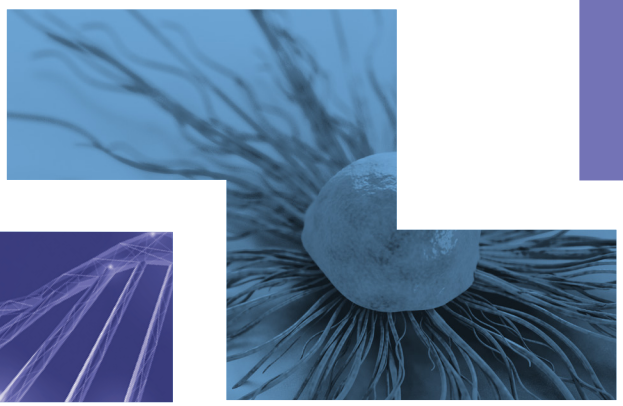


Immuno-oncology research solutions

- Ion Torrent™ Oncomine™ TCR Beta-LR Assay
- Ion Torrent™ Oncomine™ TCR Beta-SR Assay
- Ion Torrent™ Oncomine™ Tumor Mutation Load Assay

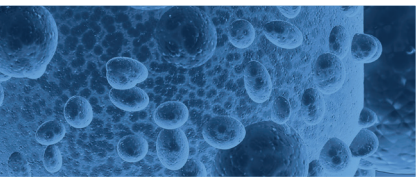






Liquid biopsy research solutions

- Ion Torrent™ Oncomine™ cfDNA Assays for Lung, Breast, Colon
- Ion Torrent™ Oncomine™ Breast cfDNA Assay v2
- Ion Torrent™ Oncomine™ Lung Cell-Free Total Nucleic Acid Research Assay
- Ion Torrent™ Oncomine™ Pan-Cancer Cell-Free Assay

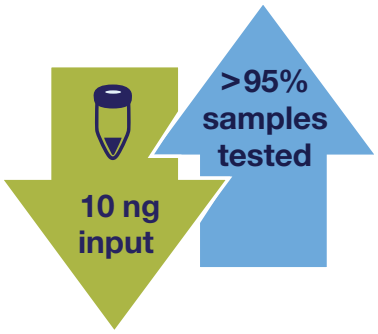


FFPE tissue testing solutions

- New: Ion Torrent™ Oncomine™ Precision Assay
- New: Ion Torrent™ Oncomine™ Comprehensive Assay Plus
- New: Ion Torrent™ Oncomine™ tumor-specific panels
- Ion Torrent™ Oncomine™ Comprehensive Assay v3
- Ion Torrent™ Oncomine™ Focus Assay
- Ion Torrent™ Oncomine™ *BRCA* Research Assay

The importance of choosing the best technology for the purpose

Low FFPE tissue sample input requirement is crucial



Formalin-fixed, paraffin-embedded (FFPE) tissue samples are often small, and the tumor content is limited in quantity and/or quality. Oncomine assays require the least input of any commercially available assay and they have a proven record of high sequencing success. This enables labs to get results for maximum possible samples and save tissue sample for possible future further analysis.

Not all NGS is the same: sample requirements can differ greatly from one test to the next

NGS-based testing input requirements are typically expressed in nanograms of nucleic acid, and can differ significantly between different NGS-based tests. The figures below explain the practical implications of these different requirements in terms of tissue, tumor area, and content. Even if similar numbers of slides are required for both tests, the tumor area and percentage of tumor content required are significantly higher for method F, in order for testing to be successful.

Method F

20% minimum,
30% optimum tumor content

25 mm^2 minimum sample surface area, entire block or 10 slides required

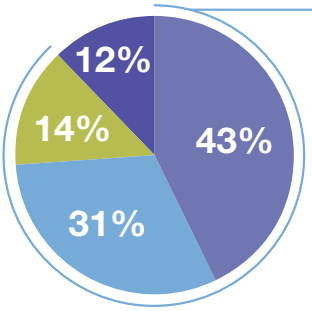
50 ng–1,000 ng minimum input

Method O

10% minimum tumor content

No minimum surface area requirement; 2 slides for resection, 9 for CNB required

10 ng minimum input required



88% of all samples had less than 25 mm^2 tumor area

Tumor area

- ≤1 mm^2
- >1 mm^2 and ≤5 mm^2
- >5 mm^2 and ≤25 mm^2
- >25 mm^2

The high sample requirement of some methods means that a significant number of research samples cannot be tested. As an example from one laboratory, out of 1,791 NSCLC samples received in one year, only 215 could be tested by method F–that means only 1 out of every 8 samples. All samples were able to be tested by method O.

Source: NGS to take top spot as cancer biomarker testing broadens. *CAP TODAY*, June 2018

Translocation/fusion detection: two sides of the story

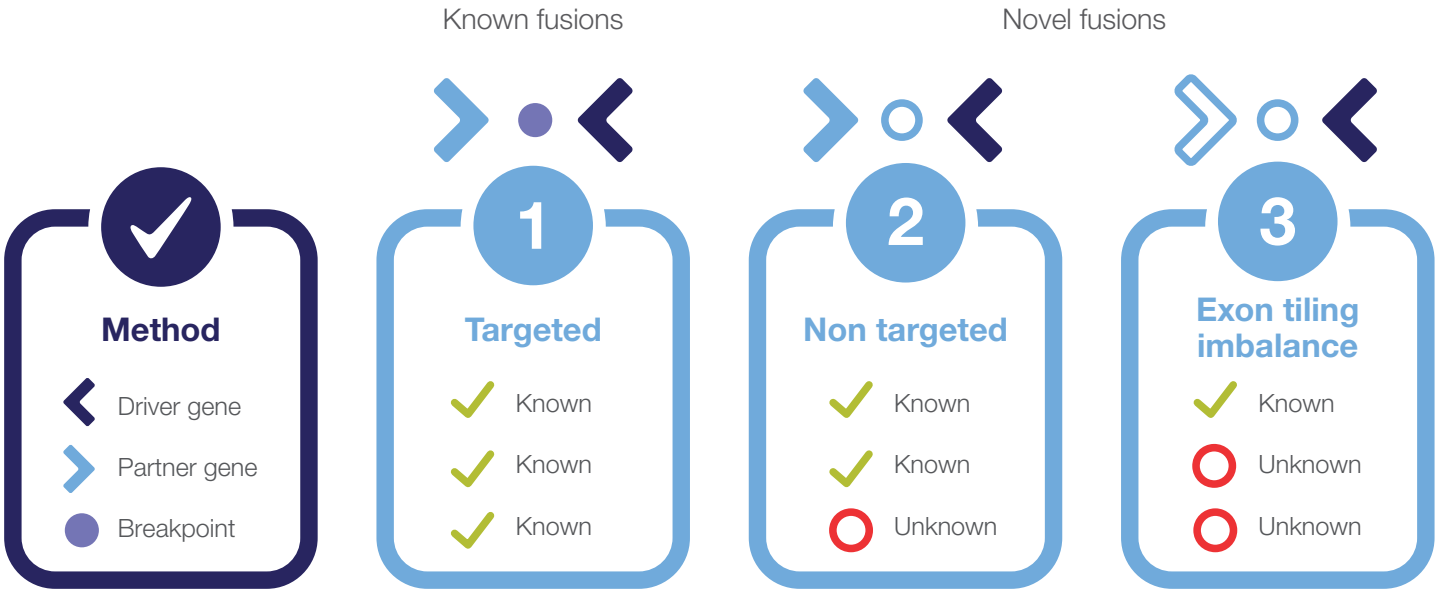
The Ion Torrent™ Oncomine™ assays include a multifunctional approach to detect gene fusions in order to achieve a proper balance of strong performance on FFPE tissue with limited RNA input and comprehensive fusion detection.

1. Targeted and therefore sensitive detection of **known and recurrent fusion** isoforms that constitute most of the fusions detected. Having specific designs for these isoforms is important to maximize their detection even in challenging situations when sample input or transcript levels are low.
2. **Detection of novel fusions,** which are rare events, is achieved by non targeted isoform detection and imbalance technology.

FusionSync™ detection technology

NEW

Now you can detect novel and rare fusions without missing the known and common. This new technology for routine fusion detection in clinical research samples is designed to improve novel fusion detection. The targeted approach employs hundreds of fusion isoforms across varying partners and breakpoints to help ensure sensitive and specific detection of known fusions. In addition, exon tiling imbalance is available for *ALK*, *FGFR1*, *FGFR2*, *FGFR3*, *NTRK1*, *NTRK2*, *NTRK3*, and *RET* fusion drivers, which indicates not only the presence of an unknown fusion but also whether it will be a functional or nonfunctional fusion based on its impact on kinase domains.

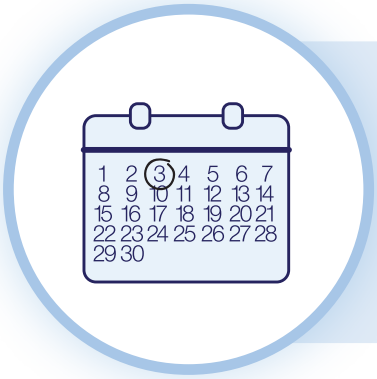


Oncomine Precision Assay on the Genexus System

NGS with the speed and simplicity of IHC

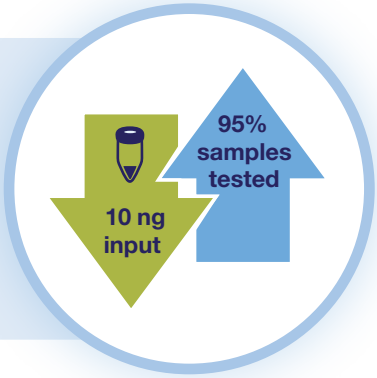
The Oncomine Precision Assay on the new Genexus System is our next-generation solution for genomic profiling that empowers labs with an automated, hands-off workflow that takes you from FFPE tissue or plasma to report in one day.*

It can be easily implemented in every lab, even without previous NGS experience, and will enable you to combine your lab's immunohistochemistry (IHC) results with an NGS profile of 50 key genes for a fast, comprehensive report.



One-day turnaround time

Less sample required, many more samples successfully tested



2 touchpoints and 10 min of hands-on time

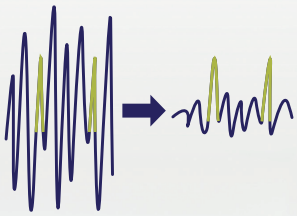
* Specimen-to-report workflow will be available after the Genexus Purification System and integrated reporting capabilities are added in 2020.

Curated pan-cancer research content

- Mutation, CNV, and fusion variant types across 50 key genes
- Tumor suppressors, drivers, and resistance variants

Tissue and plasma samples

- One test, one workflow, multiple sample types
- Maximizes samples that can be tested



Molecular tagging

- Accurate low-level variant detection
- Maximizes the number of tumors that can be profiled

Oncomine tumor-specific panels

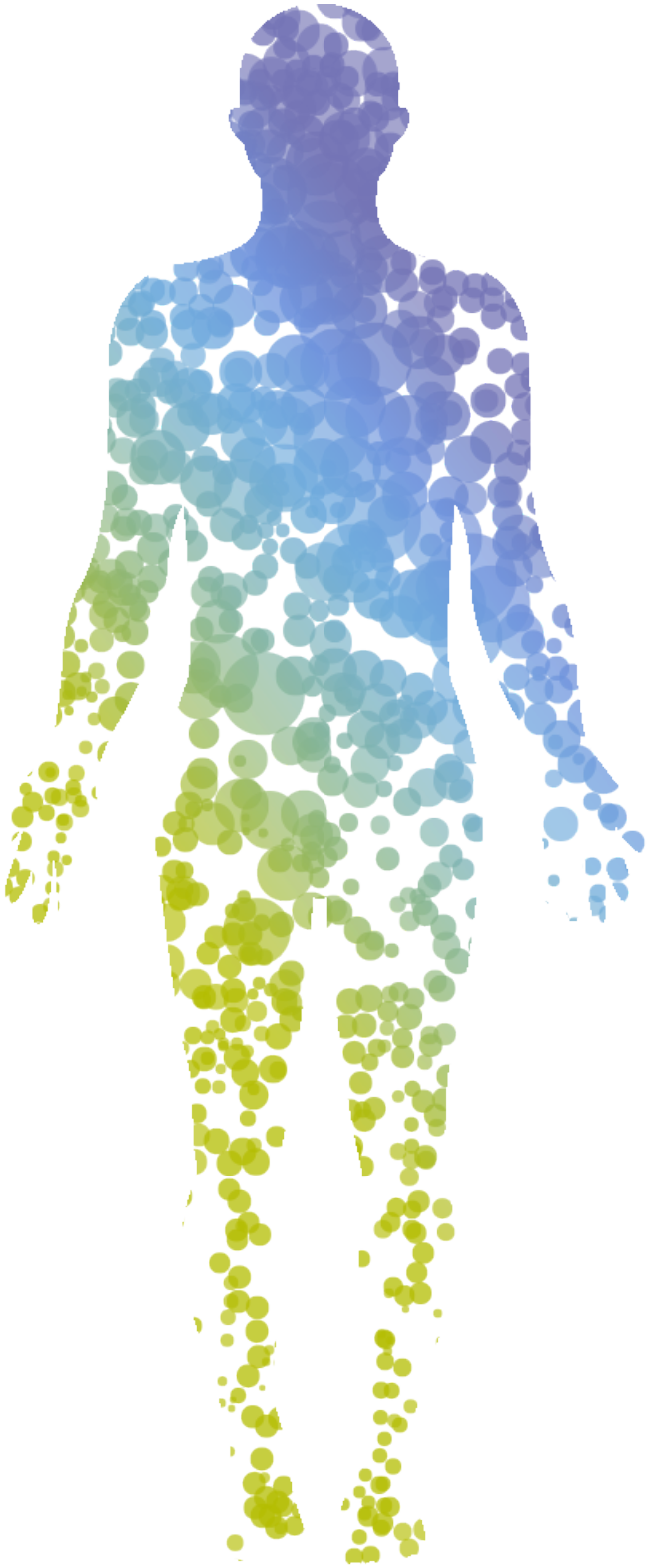
Because in precision oncology research, one size does not fit all

Choose Ion Torrent™ Oncomine™ tumor-specific panels for focused cancer research

The greater our knowledge about the genomic aberrations that may potentially cause cancer, the more we understand how heterogeneous it can be. While some aberrations can be found across many tumors, some are very specific to particular tumor types. An array of tools is required to provide relevant information for every cancer research sample while managing costs and available tissue material.

When available, Oncomine tumor-specific research panels will complement Oncomine assays, providing end-to-end solutions for researching the molecular profile of specific tumors from FFPE tissue samples.

- Small tumor-specific panels with relevant content for clinical research (15–30 genes)
- Available via **ampliseq.com** and manufactured on demand
- Low sample input requirement and robust performance on FFPE tissue
- End-to-end workflow, including bioinformatics and a reporting solution
- Specialized support for implementation



Ion Torrent™ Oncomine™ Bladder Panel

25-gene panel applicable to urothelial carcinoma, which represents ~90% of bladder cancers. Contains genes such as *PIK3CA*, *FGFR3*, and *ERBB2.*

Ion Torrent™ Oncomine™ Kidney Panel

15-gene panel applicable to renal cell carcinomas, the majority of kidney cancer. Contains genes such as *VHL*, *MTOR*, and *PBRM1*.

Ion Torrent™ Oncomine™ *BRCA* Expanded Panel

15-gene panel containing *BRCA1* and *BRCA2* as well as HR pathway genes important for ovarian, breast, and prostate cancer research. Contains genes such as *ATM, PALB2,* and *BRIP1*.

Ion Torrent™ Oncomine™ Liver Panel

22-gene panel applicable to hepatocellular carcinoma (HCC) and intrahepatic cholangiocarcinoma (ICC). Contains genes such as *TP53, MYC, TERT*, and *CTNNB1*.

Ion Torrent™ Oncomine™ Colorectal and Pancreatic Panel

24-gene panel applicable to colorectal and pancreatic adenocarcinoma, including DNA mismatch repair pathway genes. Contains genes such as *APC, KRAS,* and *NRAS*.

Ion Torrent™ Oncomine™ Lymphoma Panel

25-gene panel applicable to non-Hodgkin's lymphomas (primarily diffuse large B cell (DLBCL)) as well as to Hodgkin's lymphoma. Contains genes such as *BCL2, MYD88*, and *CARD11*.

Ion Torrent™ Oncomine™ Gastric and Esophageal Panel

17-gene panel applicable to gastric, esophageal, and gastroesophageal adenocarcinoma. Contains genes such as *TP53, ERBB2,* and *CDKN2A.*

Ion Torrent™ Oncomine™ Melanoma Panel

30-gene panel applicable to cutaneous and uveal melanoma. Contains genes such as *BRAF, NRAS,* and *CDKN2A*.

Ion Torrent™ Oncomine™ Gynecological Panel

19-gene panel applicable to endometrial, cervical, and ovarian carcinomas. Contains genes such as *PTEN, BRCA2,* and *CTNNB1*.

Ion Torrent™ Oncomine™ Prostate Panel

21-gene panel applicable to prostate adenocarcinoma. Contains genes such as *AR, PTEN,* and *MYC.*

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Oncomine Comprehensive Assay Plus

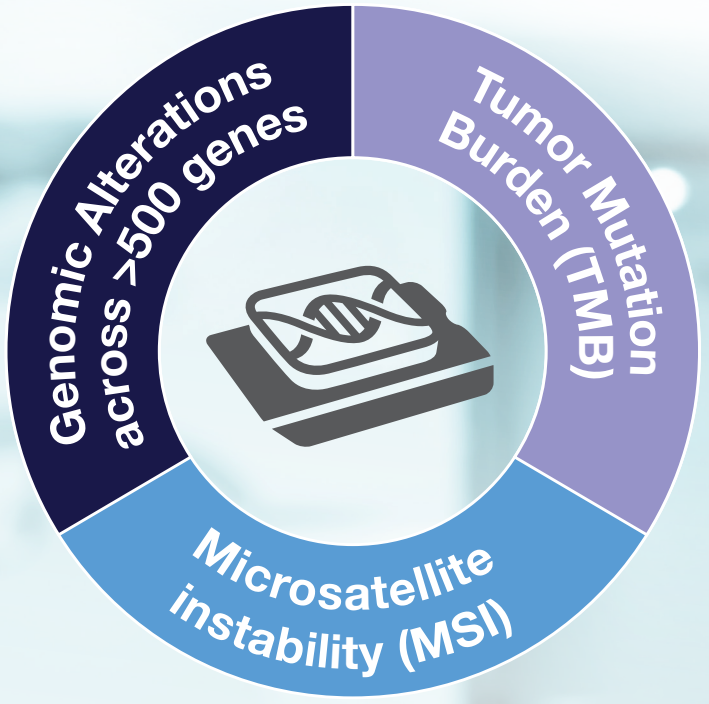
Comprehensive genomic profiling without compromises

Precision oncology research is quickly developing beyond single-biomarker profiling towards also assessing complex biomarkers. While this approach is still more prevalent in clinical research and not justified for every sample, it is important to be able to gain all of these genomic insights at once, when relevant.

The Oncomine Comprehensive Assay Plus is a broad, >500-gene assay that enables comprehensive genomic profiling by combining tumor mutational burden (TMB) and microsatellite instability (MSI) in a single assay.

This multibiomarker assay includes driver genes across all solid tumors, interrogates all classes of genomic alteration, and is enriched with gene variants to give you relevant insights.

- Minimum sample input
- Maximum results



Only 10 ng of input required, meaning many more samples can be analyzed

All classes of genomic alterations, including SNVs, indels, fusions, and CNVs across tumor types

End-to-end informatics solution with Oncomine Reporter

Simplify your journey to answers in hemato-oncology research

The tools you need to expedite your path to hemato-oncology research insights in one place

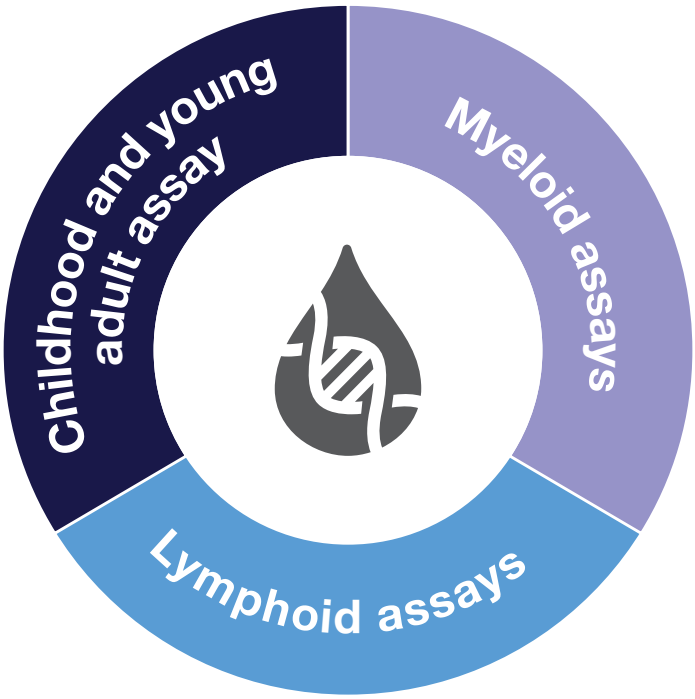
Hemato-oncological disorders are complex and heterogenous diseases with many oncogenic drivers and subtypes.

Traditionally, the molecular research of myeloid and lymphoid malignancies have involved numerous single-gene tests, multiple technologies, and laborious workflows.

In-house NGS testing enables you to consolidate and streamline your workflows, providing faster turnaround time (TAT), higher sensitivity, and potentially higher detection yield.

Simplify and accelerate your research with our growing portfolio of hemato-oncology research assays. We make it easy for you to get everything you need in one place.

- 1 dedicated NGS partner
- 1 familiar workflow
- 1 comprehensive hemato-oncology research solution



Oncomine Childhood Cancer Research Assay

Oncomine Myeloid Research Assay
New: Oncomine Myeloid MRD Assay*

New: Oncomine BCR IGH-LR Assay*
New: Oncomine BCR IGH-SR Assay*
New: Oncomine Lymphoma Assay*
Oncomine TCR Beta-SR

* The content provided herein may relate to products that have not been officially released and is subject to change without notice.
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End-to-end bioinformatics solution

The Ion Torrent™ Oncomine™ informatics workflow presents a sample-to-report solution for data analysis, from initial sequence analysis of many variants to annotation of relevant cancer drivers, and a final report by Oncomine Reporter. This creates a simple, streamlined solution that doesn't require any specialized bioinformatics expertise.

Oncomine informatics workflow

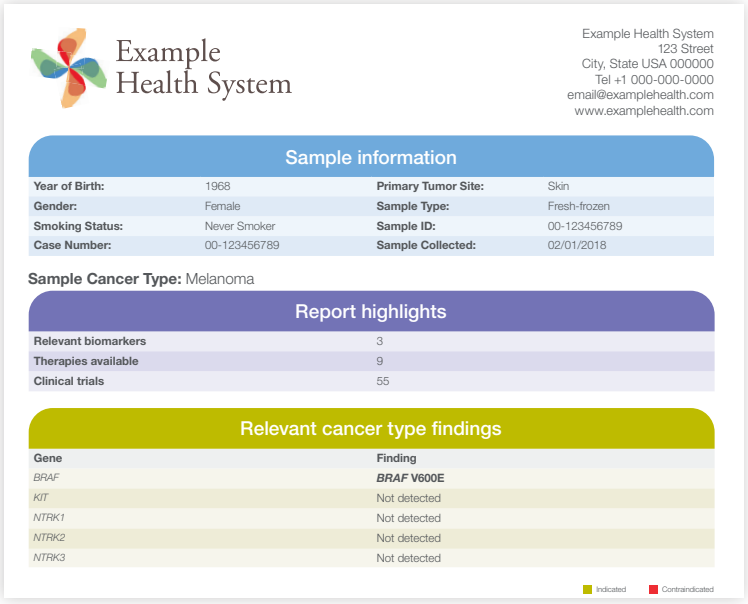
Analyze sequence: Torrent Suite™ Software streamlines sequencing runs and creates BAM files

Annotate and filter: Ion Reporter Software calls variants; identifies and annotates cancer drivers

Oncomine Reporter links variants to relevant evidence in a curated knowledgebase

Oncomine Reporter software

- Oncomine Reporter software produces clear and concise reports
- Includes relevant biomarker data and associated therapies, guidelines, and global clinical trials
- Optimized for Oncomine assays across applications including FFPE tissue testing, liquid biopsy, TMB, and hematology-oncology, and cytogenetics



Example Health System

Example Health System
123 Street
City, State USA 000000
Tel +1 000-000-0000
email@examplehealth.com
www.examplehealth.com

Sample information

Year of Birth:	1968	**Primary Tumor Site:**	Skin
Gender:	Female	**Sample Type:**	Fresh-frozen
Smoking Status:	Never Smoker	**Sample ID:**	00-123456789
Case Number:	00-123456789	**Sample Collected:**	02/01/2018

Sample Cancer Type: Melanoma

Report highlights

Relevant biomarkers	3
Therapies available	9
Clinical trials	55

Relevant cancer type findings

Gene	Finding
BRAF	***BRAF* V600E**
KIT	Not detected
NTRK1	Not detected
NTRK2	Not detected
NTRK3	Not detected

Indicated Contraindicated

Relevant cancer type findings

Gene	Finding
BRAF	***BRAF* V600E**
KIT	Not detected
NTRK1	Not detected
NTRK2	Not detected
NTRK3	Not detected

Make it your own

The first page of the report can be customized to show the relevant biomarkers and variant details sections.

Templates can be customized with your logo, with custom text, and in one of 11 languages.

The report builder allows sections to be included and excluded as needed, enabling easy customization.

Relevant biomarkers

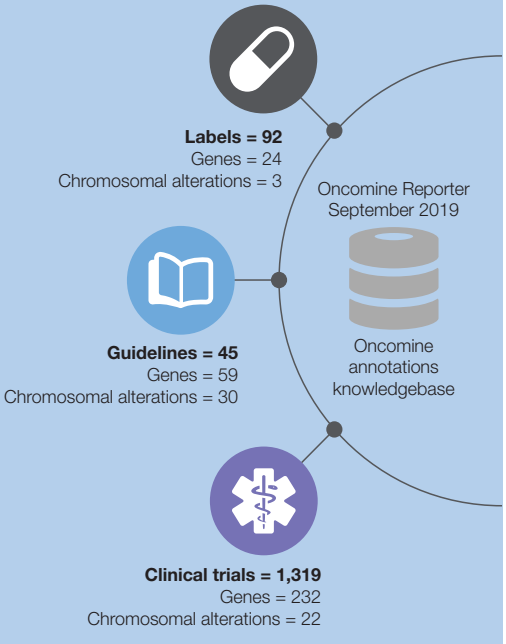
Genomic alteration	Relevant therapies (In this cancer type)	Clinical trials
BRAF V600E B-Raf proto-oncogene, serine/threonine kinase Tier: IA Allele Frequency: 20.00%	dabrafenib + trametinib[1,2] dabrafenib[1,2] trametinib[1,2] binimetinib + encorafenib[1,2] cetuximab + vemurafenib[1,2] vemurafenib[1,2] BRAF inhibitor + MEK inhibitor	55
*NF1 R2450** neurofibromin 1 Tier: IIC Allele Frequency: 28.54%	None	6
PIK3CA R88Q phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha Tier: IIC Allele Frequency: 27.15%	None	10

Get information about clinical trials

Oncomine Reporter combines the data of thousands of enrolling clinical trials from more than 50 trial registries. Information on these relevant, open clinical trials can be filtered by region, country, and state and included in your report.

Global content standardized

Ion Torrent™ Oncomine™ Knowledgebase data are meticulously curated and updated quarterly. After data are collected from various global data sources, a team of experienced curation scientists manually reviews all candidate evidence. Two independent reviewers examine each piece of candidate evidence for context and standardization. The process has QC steps built in at various stages.



When it comes to the NGS workflow, one size does not fit all

Genexus System

The new Genexus System is the first turnkey NGS solution that automates the specimen-to-report workflow and delivers results in a single day with just two user touchpoints.* The simplicity and practicality of the Genexus System means every lab can bring NGS in-house, regardless of the level of NGS expertise.

Compatible with the Oncomine Precision Assay, Oncomine Comprehensive Assay v3, Oncomine TCR Beta-LR Assay, and the Oncomine Myeloid Research Assay (coming soon).

Get results for your routine samples with one-day TAT* and minimum operational resources with the Genexus System and the Oncomine Precision Assay

* Specimen-to-report workflow will be available after the Genexus Purification System and integrated reporting capabilities are added in 2020.

Ion GeneStudio S5 System

The GeneStudio S5 system combines with the Ion Chef™ Instrument for library preparation and templating, providing a highly automated NGS workflow with scalability. A single Ion GeneStudio S5 instrument can process several different chip sizes, allowing the instrument to handle multiple levels of throughput.

Compatible with all assays from the Oncomine portfolio except the Oncomine Precision Assay.

Utilize the capacity of the Ion GeneStudio S5 instrument for projects requiring the full breadth of the Oncomine portfolio

Enable your oncology research with trusted Oncomine Solutions

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