Oncomine Solutions for precision oncology research

True end-to-end workflows for your laboratory

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

Explore our 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

Dr. Philip Jermann, PhD

Head of the Molecular Assay Development Unit of the Institute of Medical Genetics and Pathology, University Hospital Basel

"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% 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%."

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

Dr. Davide Soldini, MD, PhD

Director of the Institute of Molecular Pathology
MEDICA, Zurich

"Oncomine Solutions means to me that I can perform the analysis, basically for all the samples that we get, even with a small amount of material".

Retrieved from "What Oncomine Solutions mean to you" video

Catch up on the Oncomine Clinical Research Grant Program, new calls and awardees

The Program supports investigator-initiated studies (IIS) and education projects, on molecular testing in oncology and reproductive health, with the goal to increase high quality molecular profiling for patients and to improve clinical outcomes in the future.

Watch videos about Oncomine Solutions

Follow where you can meet us and each other

We host and participate at numerous events around the globe, and recently virtually.

See where you can meet us to see our latest solutions, discuss with our product experts, and hear from your peers about their experiences at oncomine.com/events.

Download key biomarker testing guides

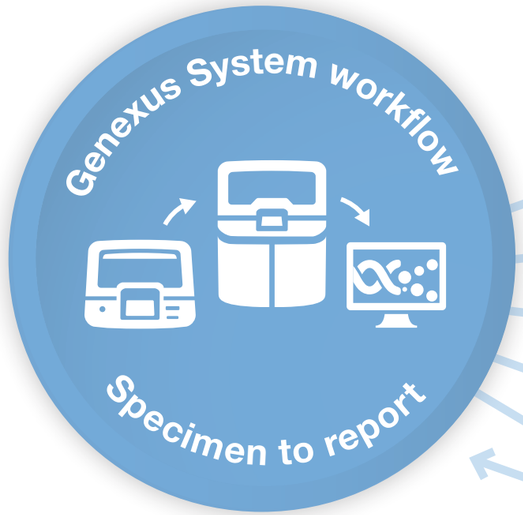
NSCLC testing guide

***PIK3CA* testing guide**

***NTRK* testing guide**

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
- Ion Torrent™ 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—Overview of all Oncomine assays across key applications

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

Hemato-oncology research solutions

- Ion Torrent™ Oncomine™ Myeloid Assay GX
- Ion Torrent™ Oncomine™ Myeloid Research Assay
- Ion Torrent™ Oncomine™ BCR Pan-Clonality Assay
- Ion Torrent™ Oncomine™ TCR Pan-Clonality Assay
- Ion Torrent™ Oncomine™ IGHV Leader-J Assay
- Ion Torrent™ Oncomine™ Lymphoma Assay
- Ion Torrent™ Oncomine™ Childhood Cancer Research Assay

Immuno-oncology research solutions

- Ion Torrent™ Oncomine™ Comprehensive Assay Plus
- Ion Torrent™ Oncomine™ Tumor Mutation Load Assay
- Ion Torrent™ Oncomine™ TCR Beta-LR Assay (GX)
- Ion Torrent™ Oncomine™ TCR Beta-SR Assay
- Ion Torrent™ Oncomine™ Immune Response Research Assay
- Ion Torrent™ Oncomine™ TCR Pan-Clonality Assay

*The content here as key to notes above for the additions to the FFPE section provided herein may relate to products that have not been officially released and is subject to change without notice.
For Research Use Only. Not for use in diagnostic procedures.

Liquid biopsy research solutions

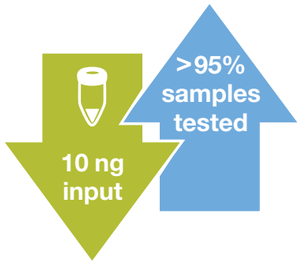
- Ion Torrent™ Oncomine™ cfDNA Assays for Lung, Breast, Colon
- Ion Torrent™ Oncomine™ Breast cfDNA Assay v2
- Ion Torrent™ Oncomine™ Lung Cell-Free Total Nucleic Acid Research Assay
- Ion Torrent™ Oncomine™ Pan-Cancer Cell-Free Assay
- Oncomine™ Precision Assay

FFPE tissue testing solutions

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

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 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 number of 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 hybrid capture-based NGS	20% minimum, 30% optimum tumor content	25 mm^2 minimum sample surface area, entire block or 10 slides required	50–1,000 ng minimum input
Method O amplicon-based NGS	10% minimum tumor content	No minimum surface area requirement; 2 slides for resection, 9 for CNB required	10 ng minimum input required

42.7%
Samples eligible for hybrid capture-based NGS

93.8%
Samples eligible for amplicon-based NGS

According to data from a multicentric study on more than 20,000 samples, more than half of all samples would not be suitable for hybrid capture-based NGS, while 93.8% of samples including those with less than 25 mm2 surface area were successfully tested by amplicon-based NGS methods***.

* Fernandes, et al. (2021) Clinical application of next-generation sequencing of plasma cell-free DNA for genotyping untreated advanced non-small cell lung cancer *Cancers* 13(11) 2707. https://doi.org/10.3390/cancers13112707

** Volckmar, A.-L. 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*, 145: 649-661. https://doi.org/10.1002/ijc.32133

*** Scott, A et al. (2020) Actionable CR-based comprehensive genomic profiling (PCR-CG P): Feasibility from >20,000 tissue specimens and predicted impact on actionable biomarker identification vs. hybrid capture (H)-CG P and plasma (P)-CGP. Presented at ASCO 2020.

Translocation and fusion detection: two sides of the story

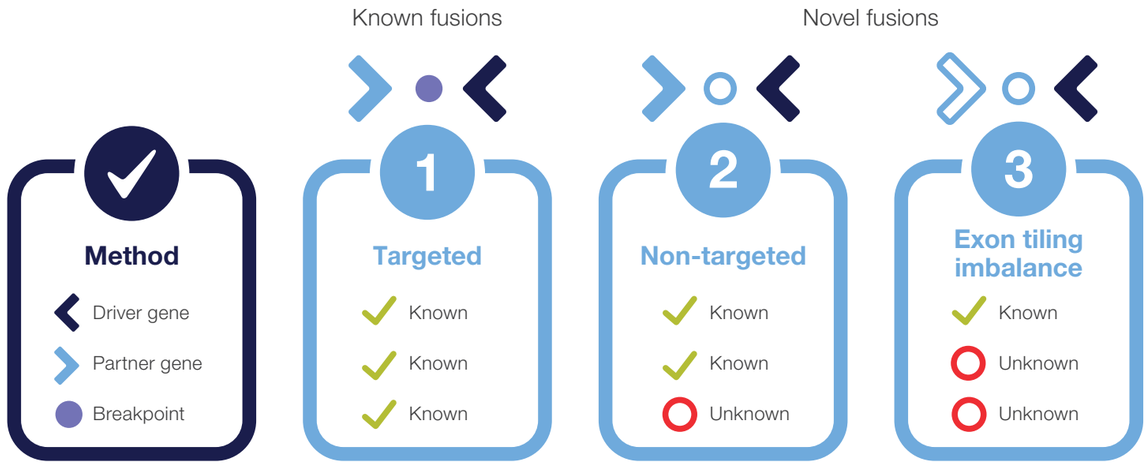
The Ion Torrent™ Oncomine™ assays include a multifunctional approach to detect and identify gene fusions in order to achieve a proper balance of strong performance on FFPE tissue with limited RNA input and comprehensive fusion detection.

Key considerations for optimal fusion detection:

1. Detection of fusion in low sample inputs
2. Detection of fusion transcripts at low levels
3. Detection of novel fusions for driver genes
4. Many technologies emphasize No. 3 above but ignore Nos. 1 and 2. With FusionSync™ detection, we address Nos. 1, 2, and 3.

FusionSync detection technology

This new technology for routine fusion detection in clinical research samples is designed to improve novel fusion detection and is available in Oncomine Precision Assay and Oncomine Comprehensive Assay Plus. 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.

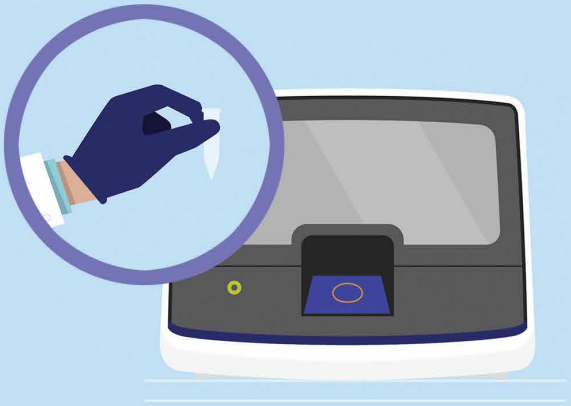


The one and only end-to-end NGS solution for any laboratory—The Genexus System

2 instruments	**1** software	**2** touchpoints
15 min hands-on time	**<24** hours turnaround time	**1** supplier and team to support you

All operated by one Ion To

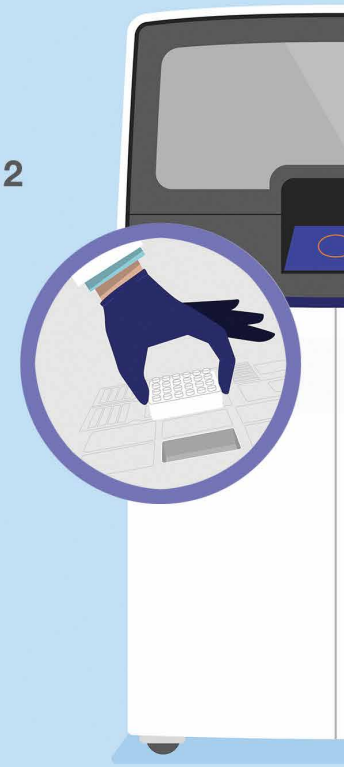
Touchpoint 1



Ion Torrent Genexus Purification System

1. Nucleic acid (NA) extraction
2. NA quantification
3. Sequencing sample plate preparation
4. Storage NA plate preparation

Touchpoint 2



Ion Torrent Gene

1. Library p
2. Templati

Currently including

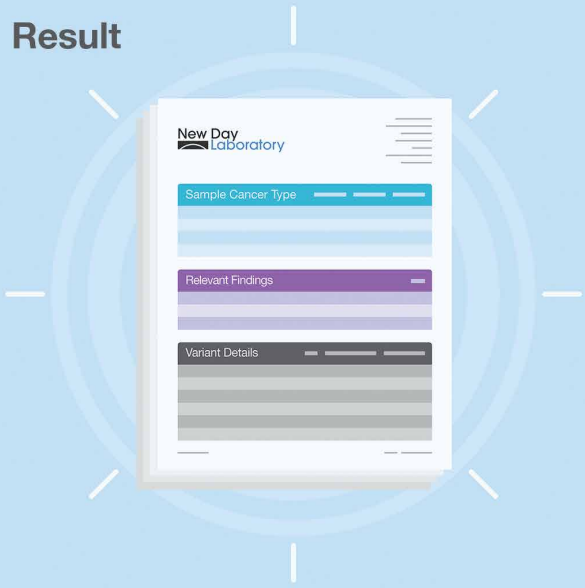
- Oncomine Precision Assay
- Oncomine Comprehensive Assay v3
- Oncomine Myeloid Assay

Oncomine TCR Beta-LR Assay

Coming Soon

- Oncomine *BRCA* Research Assay
- Oncomine Comprehensive Assay Plus

rrent™ Genexus™ Software



exus Integrated Sequencer

preparation

ng

3 Sequencing

4 Analysis

Oncomine Reporter

1 Final report

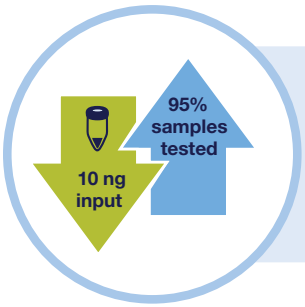
Two Oncomine flagship assays on the Genexus System– Key biomarkers in less than 1 day, with 10 min hands-on time

Oncomine Precision Assay

The Oncomine Precision Assay on the new Ion Torrent™ 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.

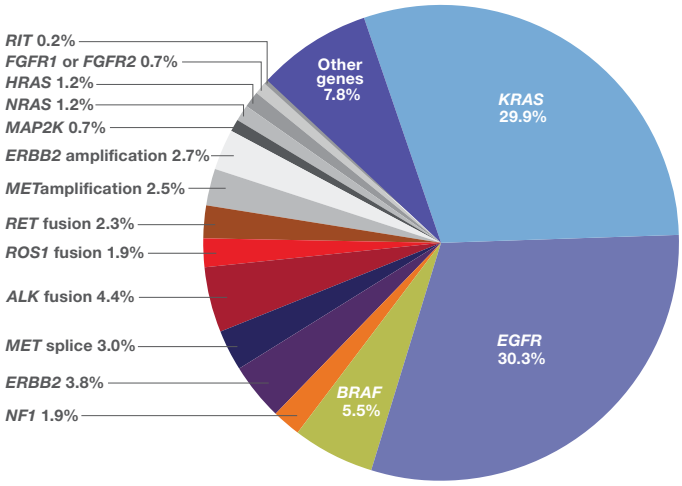
Key relevant biomarkers
across 50 key genes enable you to generate a complete relevant profile

Tissue and plasma
Enabling you to generate a profile even with a lack of tissue sample



Low sample requirement
of 10 ng means many more samples successfully tested

With the Oncomine Precision Assay
you can test all key relevant biomarkers for NSCLC clinical research either from FFPE tissue or liquid biopsy sample



* Specimen-to-report workflow will be available after the Ion Torrent™ Genexus™ Purification System and integrated reporting capabilities are added in H2 2021.

Oncomine Myeloid Assay GX

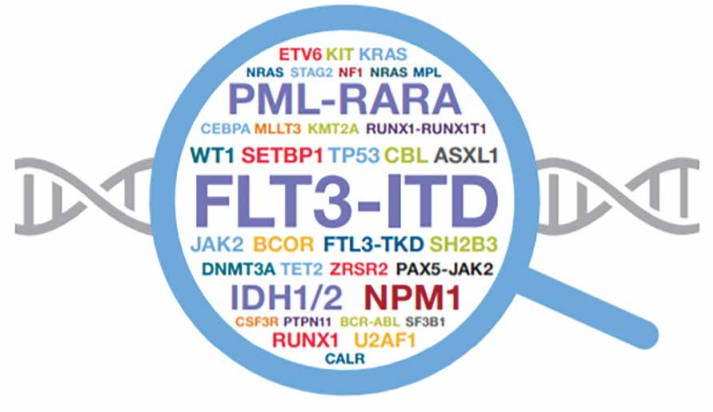
With the Oncomine Myeloid Assay GX on the Genexus System, you can get a comprehensive myeloid mutational profile and results from a single NGS run in just one day. The highly integrated workflow lets you go from specimen to report with only 10 minutes of hands-on time and two user touchpoints. Simultaneously profile 40 DNA target genes and 29 RNA fusion driver genes with a single assay. The broad fusion panel allows you to detect over 600 unique fusion isotypes.

Rapid turnaround
results in 1 day to help provide critical answers fast

Comprehensive panel of biomarkers
DNA mutations and RNA fusion transcripts with one assay

Study all major myeloid disorders
AML, MDS, MPN, CMML, and JMML

- **40 total genes**
  23 hotspot genes
  17 full genes
- **29 RNA fusion drivers**
  >600 fusion isotypes
- **5 gene expression genes**
- **5 gene expression control genes**



Comprehensive genomic profiling without compromises

Oncomine Comprehensive Assay Plus

Comprehensive genomic profiling (CGP) is advancing precision oncology research through the analysis of multiple relevant biomarkers in a single NGS test*. However, the high sample input volume requirements and other technical limitations of some hybrid capture–based NGS assays, mean that >57% of clinical research samples are not even eligible for testing**. The Oncomine Comprehensive Assay Plus provides CGP without these limitations.

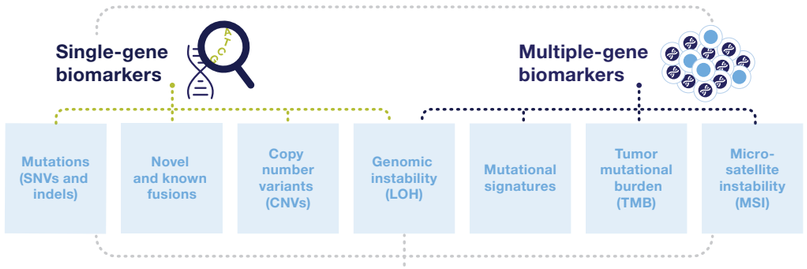
Existing tools are limited

Increasing need for genomic data
A growing amount of data generated by CGP is driving precision oncology research

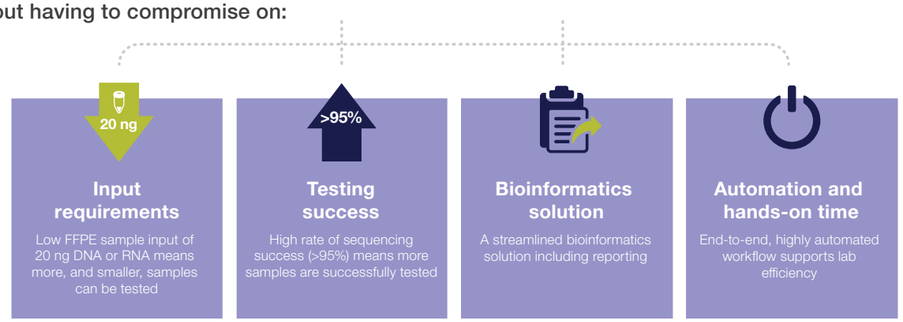
Limitations and compromises
Need for a large amount of sample to be analyzed; complex, labor-intensive workflows; and high rate of sequencing failure (>25%)

Oncomine Comprehensive Assay Plus

From one sample, in one assay run, you can deliver truly comprehensive genomic profiling based on DNA and RNA analysis of >500 genes ...



... without having to compromise on:



* Bubendorf, L et al. (2017) Non-small cell lung carcinoma: diagnostic difficulties in small biopsies and cytological specimens. *European Respiratory Review.* 26(144)17007 DOI: 10.1183/16000617.0007-2017

** Rhodes, D (2020) PCR-based comprehensive genomic profiling (PCR-CGP): feasibility from >20,000 tumor tissue specimens (TTS) and predicted impact on actionable biomarker identification versus hybrid capture (H)-CGP and plasma (P)-CGP. *Journal of Clinical Oncology.* 38(15) 3574.

Simplified journey to answers in hemato-oncology research

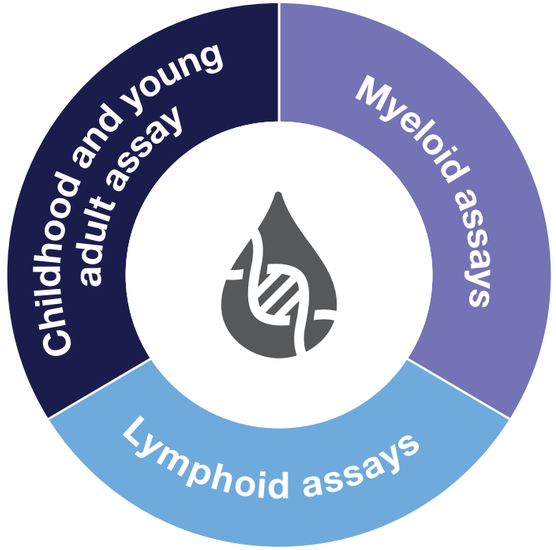
The tools you need to expedite your path to hemato-oncology research insights in one place

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

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

In-house NGS testing enables you to consolidate and streamline your workflows, providing faster turnaroundtime (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 assay menu for hemato-oncology research



Oncomine Childhood Cancer Research Assay

Oncomine Myeloid Research Assay
Oncomine Myeloid Assay GX

Oncomine IGHV Leader-J Assay
Oncomine Lymphoma Assay*
Oncomine TCR Beta-SR Assay

End-to-end bioinformatics solution

The 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

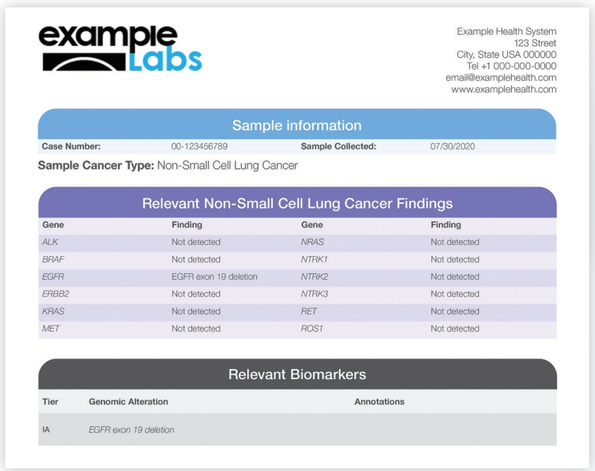
Analysis of the sequence: Torrent Suite™ Software streamlines sequencing runs and creates BAM files

Annotation 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 with relevant evidence
- Optimized for Oncomine assays across applications including FFPE tissue testing, liquid biopsy, TMB, and hemato-oncology, and cytogenetics



example Labs

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

Sample information

Case Number:	00-123456789	**Sample Collected:**	07/30/2020

Sample Cancer Type: Non-Small Cell Lung Cancer

Relevant Non-Small Cell Lung Cancer Findings

Gene	Finding	Gene	Finding
ALK	Not detected	*NRAS*	Not detected
BRAF	Not detected	*NTRK1*	Not detected
EGFR	EGFR exon 19 deletion	*NTRK2*	Not detected
ERBB2	Not detected	*NTRK3*	Not detected
KRAS	Not detected	*RET*	Not detected
MET	Not detected	*ROS1*	Not detected

Relevant Biomarkers

Tier	Genomic Alteration	Annotations
IA	*EGFR exon 19 deletion*	

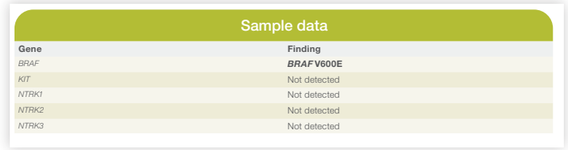
* Sakai K, et al. (2019) A comparative study of curated contents by knowledge-based curation system in cancer clinical sequencing. *Sci Rep.* 9(1):11340. Published 2019 Aug 5. doi:10.1038/s41598-019-47673-9

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 eleven languages.

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



Sample data

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

Rely on the data

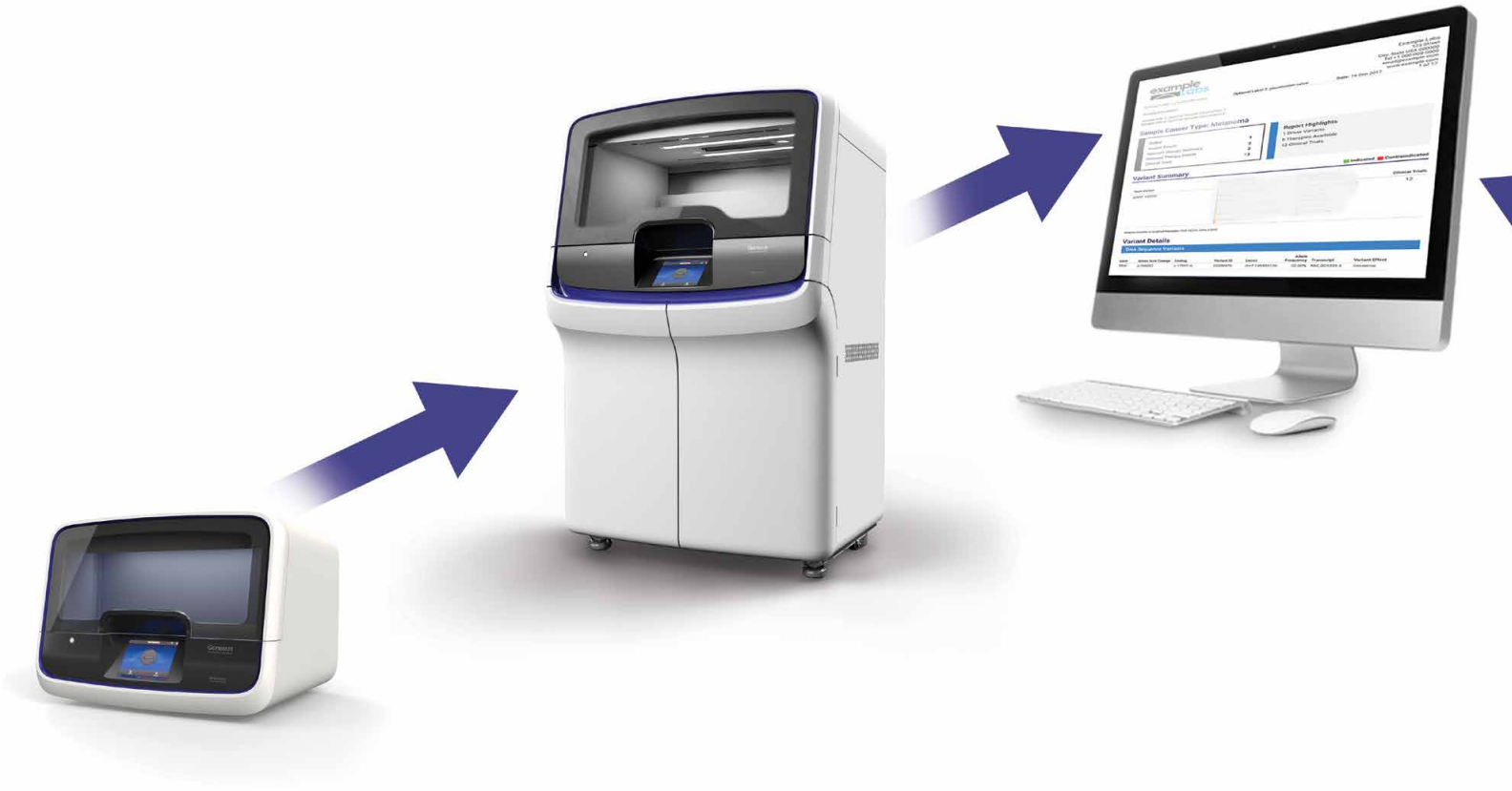
Monthly updated data

- Ion Torrent™ Oncomine™ Knowledgebase data, based on which filtration and annotation of the sequencing data are done, are updated monthly.

Meticulous curation and QC

- 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.

Also, 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.

The Genexus System is compatible with the Oncomine Precision Assay, Oncomine Comprehensive Assay v3, Oncomine TCR Beta-LR Assay, and the Oncomine Myeloid Research Assay.

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

Ion GeneStudio S5 System

The Ion 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.

The Ion GeneStudio S5 System is 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

Explore Oncomine Solutions at **oncomine.com**