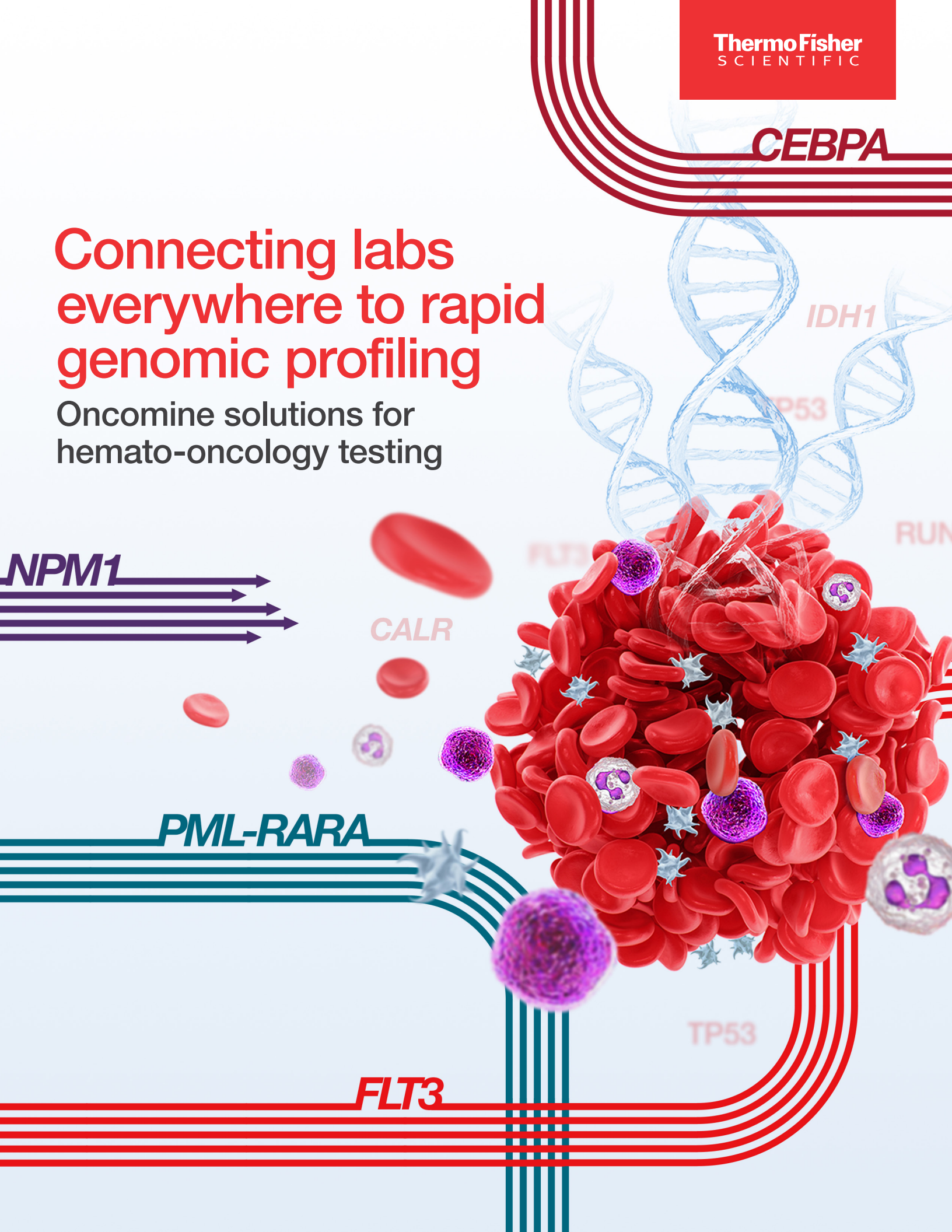
ThermoFisher SCIENTIFIC

Connecting labs everywhere to rapid genomic profiling

Oncomine solutions for hemato-oncology testing



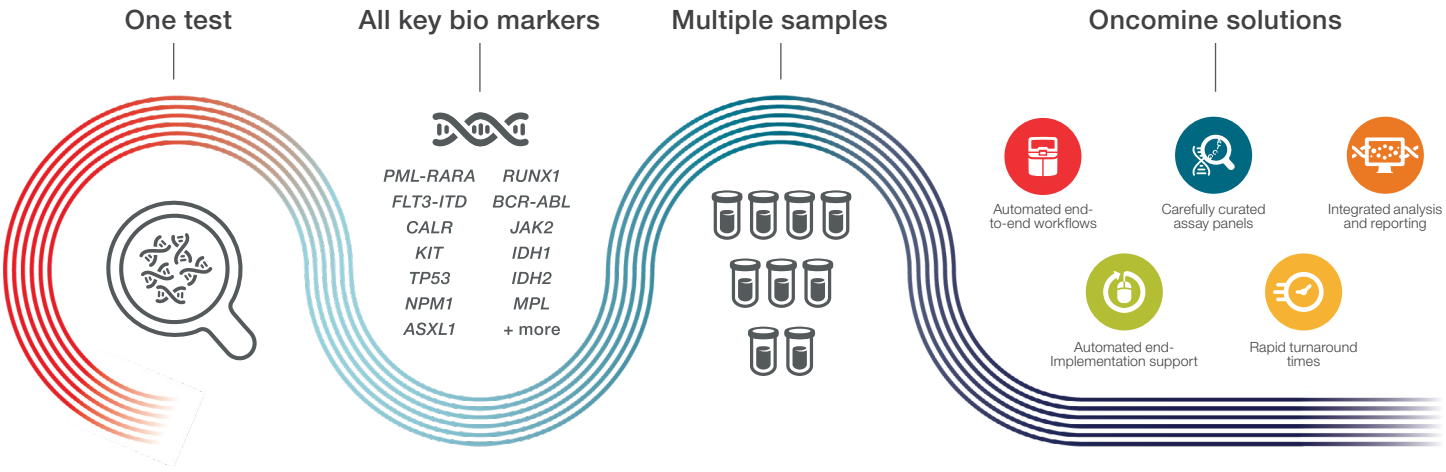
Hematologic malignancies

Hematological disorders are complex, heterogeneous diseases with many oncogenic drivers and subtypes. Acute malignancies are very aggressive and can proliferate rapidly. Getting fast, accurate, and meaningful insights is essential in helping to advance our understanding of these disorders.

Traditionally, the study of myeloid and lymphoid malignancies involved numerous single-gene tests, multiple technologies, and fragmented workflows, which can be very time-consuming and laborious.

Next-generation sequencing (NGS) overcomes these challenges by enabling labs to detect all relevant genetic alterations simultaneously in a massively parallel fashion. NGS generally provides higher sensitivity, larger scale, and the ability to detect novel aberrations compared to traditional methods.

Each year, an estimated 1.28 million people are diagnosed with a blood cancer, accounting for nearly 7% of all new cancer cases worldwide.[1]

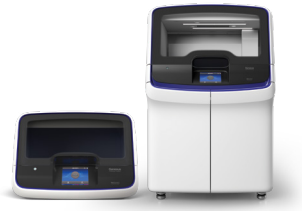


Oncomine Solutions help accelerate the path to answers

Gain more detailed insights quickly and easily with Oncomine™ Solutions. Our NGS platforms provide complete workflows that seamlessly take you from biological sample to annotated variant report. Access a broad menu of assays enabling key research applications to meet the needs of your lab. Integrated software tools simplify and automate informatics and reporting to ease the interpretation of results. As your trusted supplier, we will support you every step of the way.

The power of NGS with workflow simplicity for any lab

Our sequencing platforms are designed to be easy, so that any lab can access the power of NGS—even those with no prior experience. NGS workflow automation provides push-button simplicity to deliver results quickly with little hands-on time required.



Genexus System

Specimen to report in a single day with a highly automated workflow

The Ion Torrent™ Genexus™ System is a turnkey NGS solution that automates the specimen-to-report workflow and delivers next-day results with just two user touchpoints.

Ion GeneStudio S5 System

Scalable, targeted NGS to support small and large projects

The Ion GeneStudio™ S5 System combined with the Ion Chef™ Instrument is a scalable, targeted NGS workhorse with wide application breadth and throughput capability, and exceptional customization flexibility.

1. Hyuna Sung, PhD, et al., Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries (CA: A Cancer Journal for Clinicians, 2021), https://acsjournals.onlinelibrary.wiley.com/doi/epdf/10.3322/caac.21660.

An assay portfolio designed to cover the spectrum of hemato-oncology research applications

Ion Torrent™ Oncomine™ assays are powering molecular testing in leading labs the world over. Whether you're interested in genomic profiling for myeloid or lymphoid malignancies or immune repertoire analysis, we provide a comprehensive suite of tools to help simplify and expedite your path to answers.

Choose the NGS research solution you need from a trusted supplier dedicated to making the world healthier, cleaner, and safer.

The hematology-oncology research assay portfolio

Genomic profiling

Myeloid

- Ion Torrent™ Oncomine™ Myeloid Research Assay
- Ion Torrent™ Oncomine™ Myeloid Assay GX v2
- Ion Torrent™ Oncomine™ Myeloid MRD Assays (RUO)

Young adults and children

- Ion Torrent™ Oncomine™ Childhood Cancer Research Assay

Lymphoid

- Ion Torrent™ Oncomine™ Lymphoma Panel
- Ion AmpliSeq™ Liverpool Lymphoid Network Panel

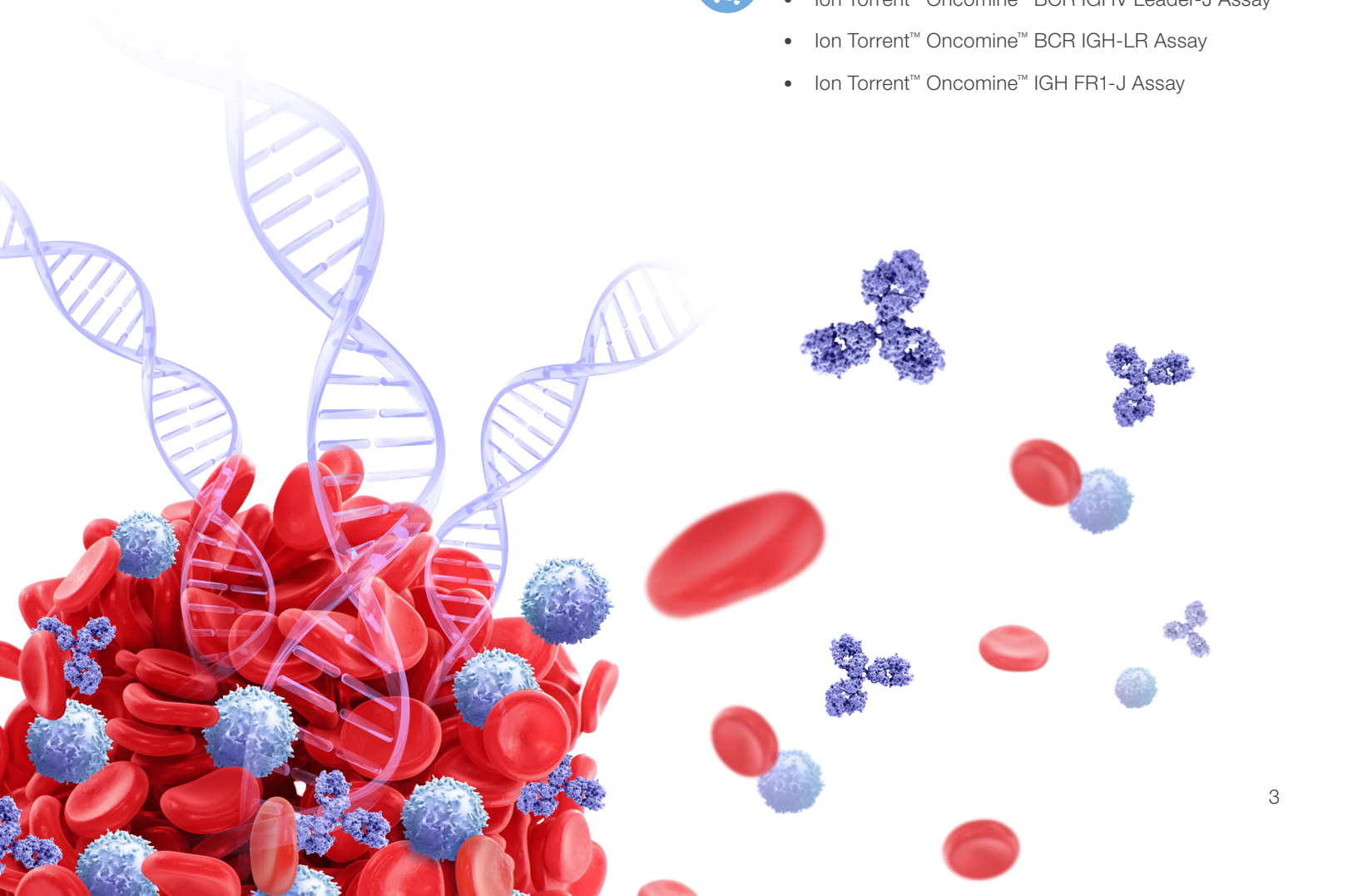
Immune repertoire analysis

Clonality and rare clone detection

- Ion Torrent™ Oncomine™ BCR Pan-Clonality Assay
- Ion Torrent™ Oncomine™ BCR IGH-SR Assay
- Ion Torrent™ Oncomine™ IGH FR3(d)-J Assay
- Ion Torrent™ Oncomine™ IGH FR2-J Assay
- Ion Torrent™ Oncomine™ TCR Pan-Clonality Assay
- Ion Torrent™ Oncomine™ TCR Beta-SR Assay
- Ion Torrent™ Oncomine™ TCR Beta-LR Assay

Somatic hypermutation

- Ion Torrent™ Oncomine™ BCR IGHV Leader-J Assay
- Ion Torrent™ Oncomine™ BCR IGH-LR Assay
- Ion Torrent™ Oncomine™ IGH FR1-J Assay



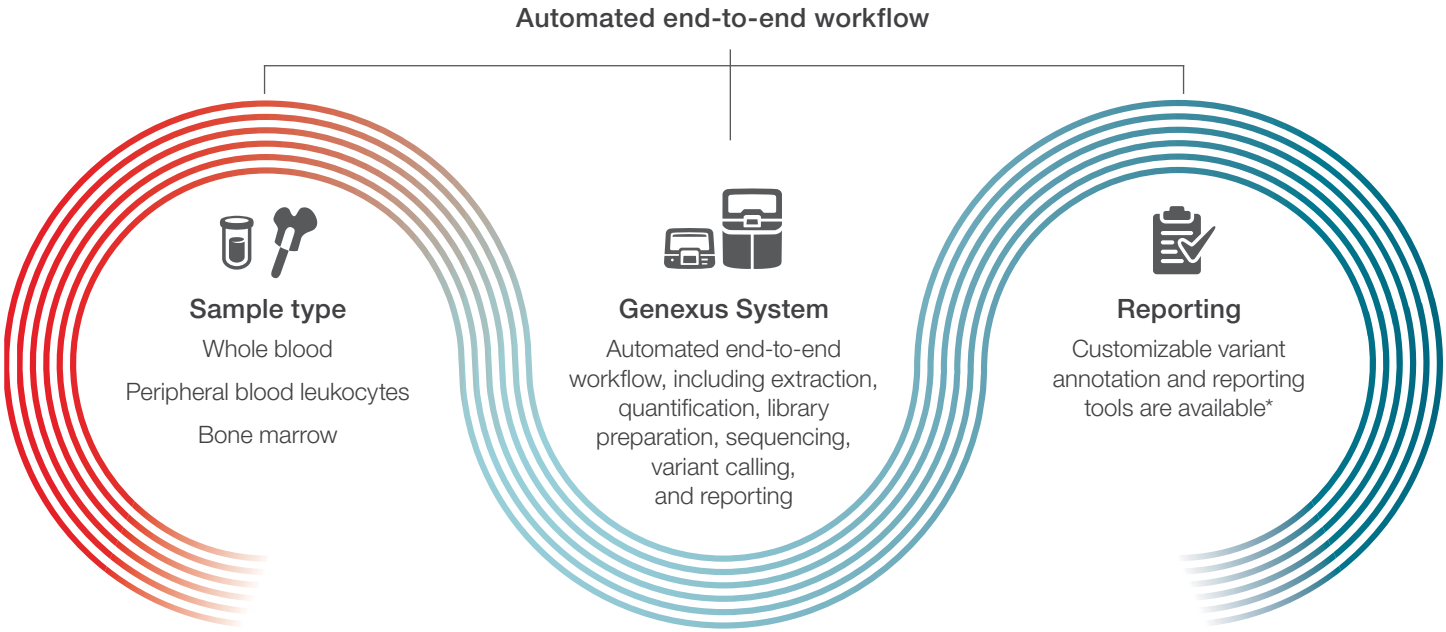
Discover our suite of hematology-oncology research NGS assays

Oncomine Myeloid Assay GX v2—achieve overnight myeloid results

The Oncomine Myeloid Assay GX v2 on the Genexus System provides a comprehensive report of myeloid mutations in as little as one day. A highly automated workflow lets you go from specimen to report with only 20 minutes of hands-on time. Sequence both DNA and RNA inputs to reliably detect all important mutations associated with myeloid malignancies.

Key features of the Oncomine Myeloid Assay GX v2

Applications	Assay inputs	Gene targets	TAT	Performance	System
Genomic profiling, gene fusion analysis	As little as 10 ng of input DNA or RNA per pool from whole blood, peripheral blood leukocytes (PBLs), or bone marrow	28 hotspot genes (DNA) 17 full genes (DNA) 34 fusion driver genes (RNA)	<27 hours	≥99% sensitivity ≥99% specificity	Genexus System



*Reporting solutions include Oncomine Reporter, the laboratory's own software, or other third-party software.

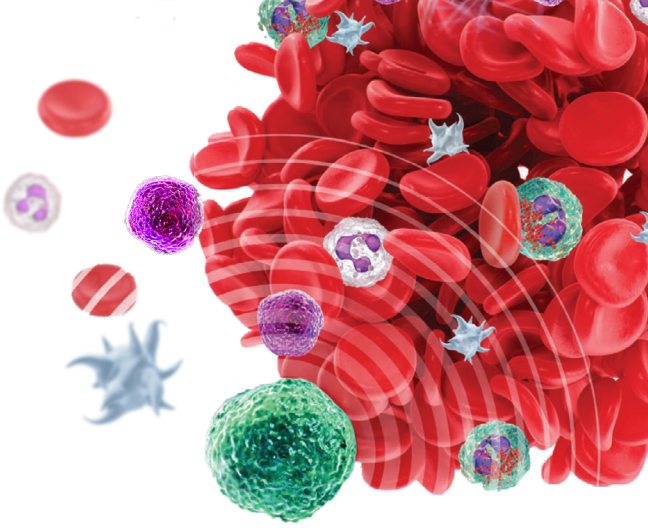
Oncomine Myeloid Research Assay—analyze DNA and RNA simultaneously

The Oncomine Myeloid Research Assay is a comprehensive assay that enables simultaneous assessment of both DNA and RNA in a single step.

- Profile 40 key DNA target genes and 29 fusion driver genes (~700 unique gene fusions)
- Gain critical insights into challenging targets, such as *FLT3-ITD* and *CEBPA*
- Access a simple workflow that delivers clear, concise, and customized reports

Key features of the Oncomine Myeloid Research Assay

Applications	Assay inputs	Gene targets	TAT	Performance	System
Genomic profiling, gene fusion analysis	As little as 10 ng of input DNA or RNA per pool from blood or bone marrow	23 hotspot genes (DNA) 17 full genes (DNA) 29 fusion drivers (RNA)	2–3 days	Expected variant detection down to 5% allele frequency with 99% confidence	Ion GeneStudio S5 System



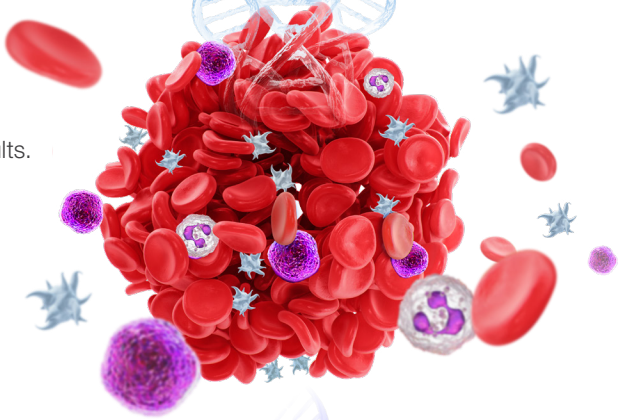
Oncomine Myeloid MRD Assays (RUO)—assays for efficient and sensitive variant detection

Oncomine Myeloid MRD Assays (RUO) offer a complete NGS solution for myeloid measurable residual disease (MRD) detection. Highlights include:

- **Comprehensive gene panels**—DNA and RNA targets relevant for myeloid MRD (SNVs, indels, fusions, and tandem duplications)
- **High sensitivity**—Ion AmpliSeq™ HD technology enables variant detection down to 0.05% allele frequency (AF)
- **Optional chimerism analysis**—highly sensitive detection of donor–recipient mixtures (as low as 0.2% AF)

Key features of Oncomine Myeloid MRD Assays (RUO)

Applications	Assay inputs	Gene targets	TAT	Performance	System
MRD detection	10 ng RNA (1 pool) 120 ng DNA (60 ng in pool 1, 60 ng in pool 2)	33 gene targets (DNA) 42 fusion drivers (RNA)	2–3 days	>95% of amplicons can reach 0.1% AF. Increasing sequencing depth and input can further boost sensitivity to 0.05%.	Ion GeneStudio S5 System



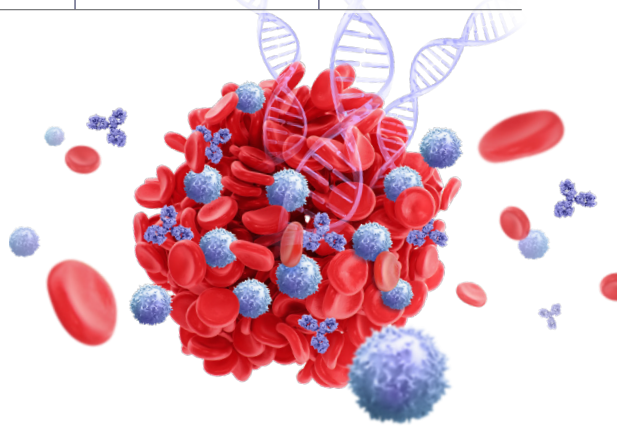
Oncomine Childhood Cancer Research Assay—study cancers in children and young adults comprehensively

The Oncomine Childhood Cancer Research Assay is designed for comprehensive genomic profiling of cancers affecting children and young adults.

- Profile 203 unique genes and thousands of fusions to help advance the future of pediatric oncology
- Target key genes relevant to leukemia research

Key features of the Oncomine Childhood Cancer Research Assay

Applications	Assay inputs	Gene targets	TAT	Performance	System
Genomic profiling	As little as 10 ng/pool input DNA or RNA per library from FFPE tissue, blood, or bone marrow	203	2–3 days	≥99% specificity ≥99% sensitivity	Ion GeneStudio S5 System



Oncomine Lymphoma Panel—robust performance for your lymphoma studies

The Oncomine Lymphoma Panel contains 25 key genes associated with all major B cell lymphomas.

- Easily tailor the assay to fit your specific research needs with additional genes from the inventory of pre-validated designs
- Get robust performance for key genes like *BCL2, MYD88,* and *CARD11,* starting with as little as 20 ng of nucleic acid

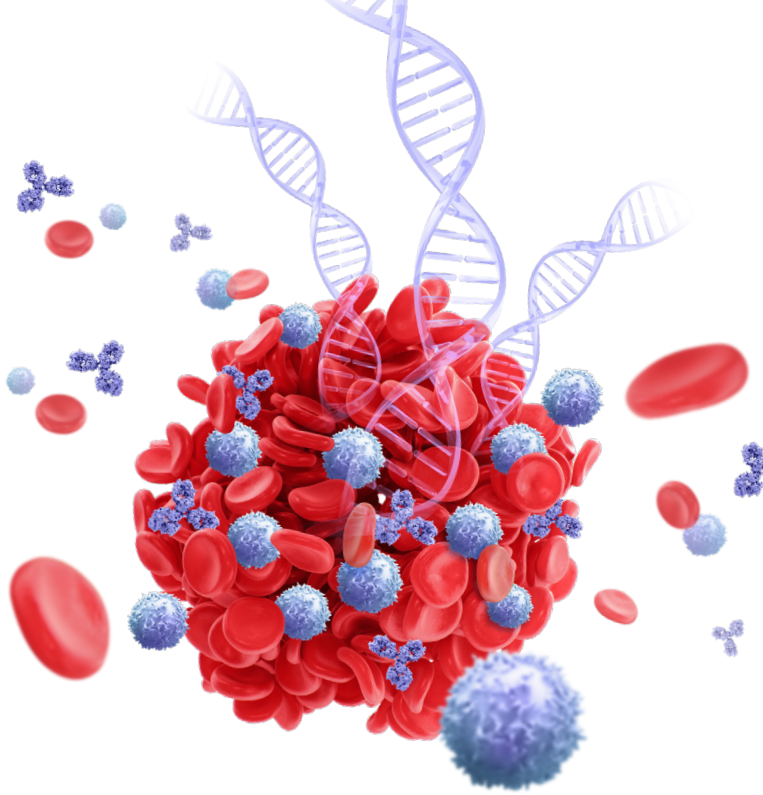
Key features of the Oncomine Lymphoma Panel

Applications	Assay inputs	Gene targets	TAT	Performance	System
Genomic profiling	20 ng input DNA from FFPE tissue, blood, bone marrow	25	2–3 days	≥99% specificity ≥99% sensitivity	Ion GeneStudio S5 System

Ion AmpliSeq Liverpool Lymphoid Network Panel—assess a range of lymphoid disorders in a single test

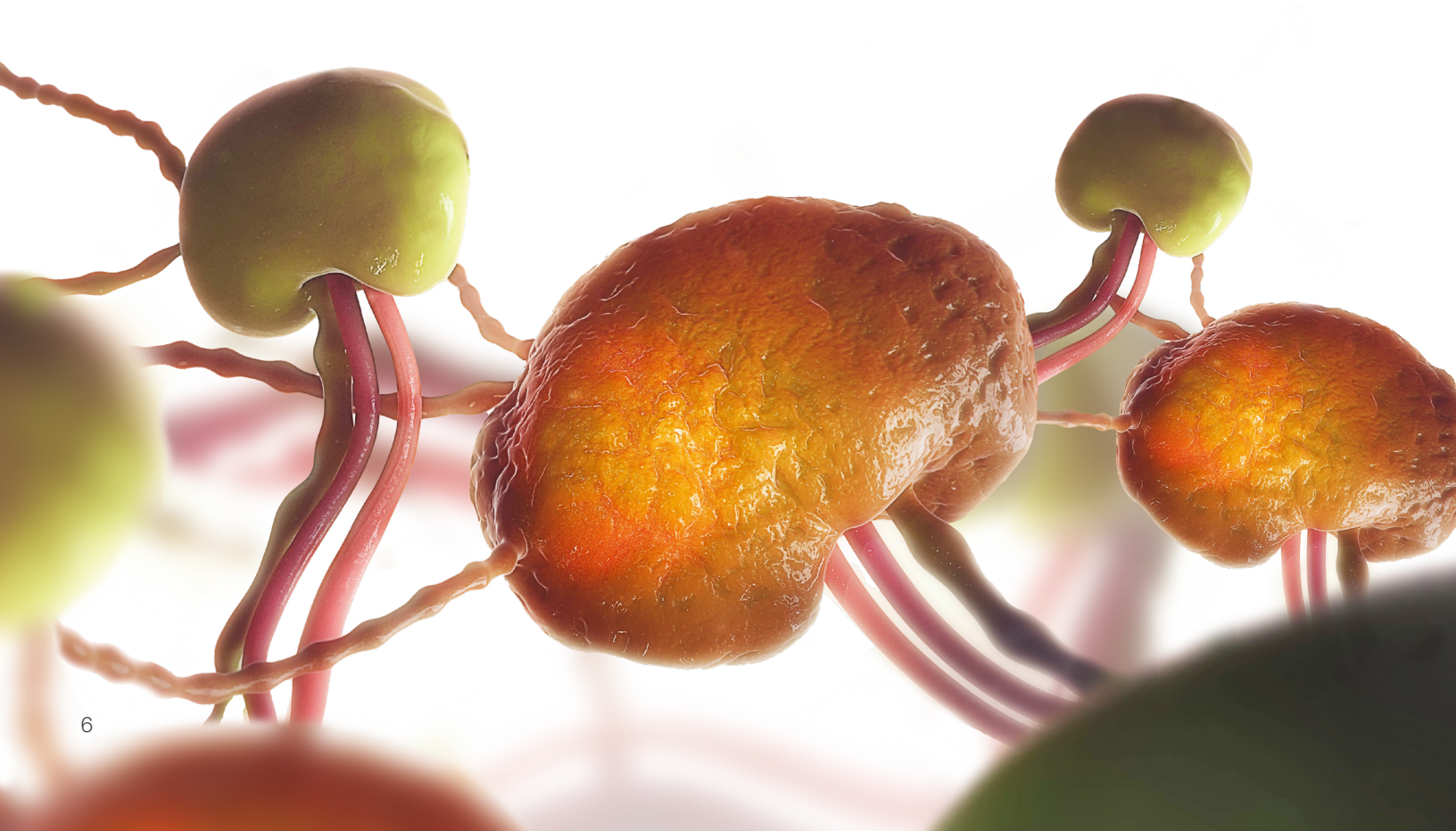
The Ion AmpliSeq Liverpool Lymphoid Network Panel is a community panel designed by leading clinical researchers for the genomic profiling of lymphoid malignancy samples.

- Simultaneously profile 60 key DNA mutations relevant for T-cell and B-cell lymphomas, leukemias, and other lymphoproliferative neoplasms
- Go from specimen to result in as little as one day
- Process samples with minimal hands-on time required, available on both GeneStudio and Genexus systems
- Reliably detect variants using a panel designed and tested by community users with real-world clinical research samples

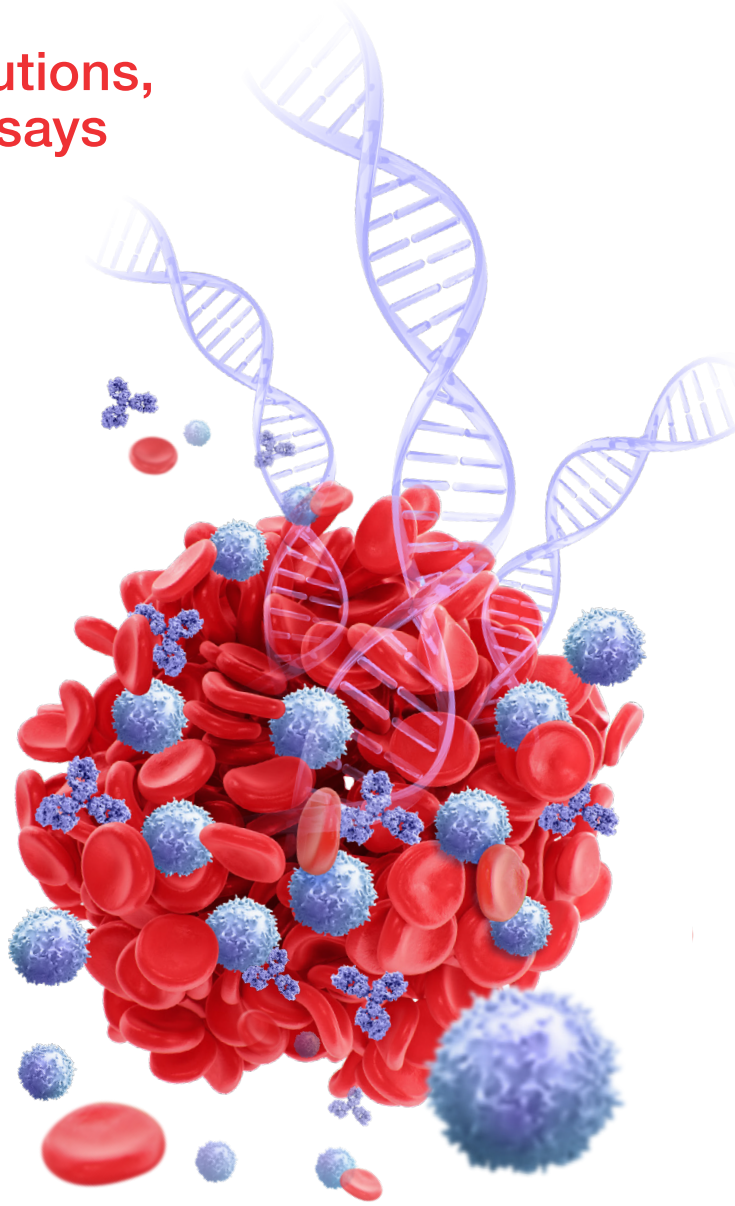


Key features of the AmpliSeq Liverpool Lymphoid Network Panel

Applications	Assay inputs	Gene targets	TAT	Performance	System
Genomic profiling	Minimum 20 ng of DNA (10 ng per pool) from peripheral blood lymphocytes, bone marrow, and FFPE tissue	60 DNA targets	Genexus: as little as 1 day GeneStudio: 2-3 days	Genexus: Uniformity 92.5% at mean depth of coverage 2347x GeneStudio: Uniformity 96% at a mean depth of coverage 2970x	Genexus System Ion GeneStudio S5 System



Immune repertoire research solutions, Clonality and MRD detection assays



Oncomine BCR Pan-Clonality Assay—assess clonality and detect measurable residual disease (MRD)

This powerful and sensitive NGS assay can accurately assess clonality and detect residual disease in a range of B cell malignancy sample types.

- Sequence multiple receptor targets in a single reaction: IGH, IGK, and IGL rearrangements, as well as kappa-deleting element (KDE) rearrangements
- Enables reliable results with >90% positive clonality detection rates
- Detect rare B cell clones with high sensitivity and an ultralow limit of detection down to 10^{-6}

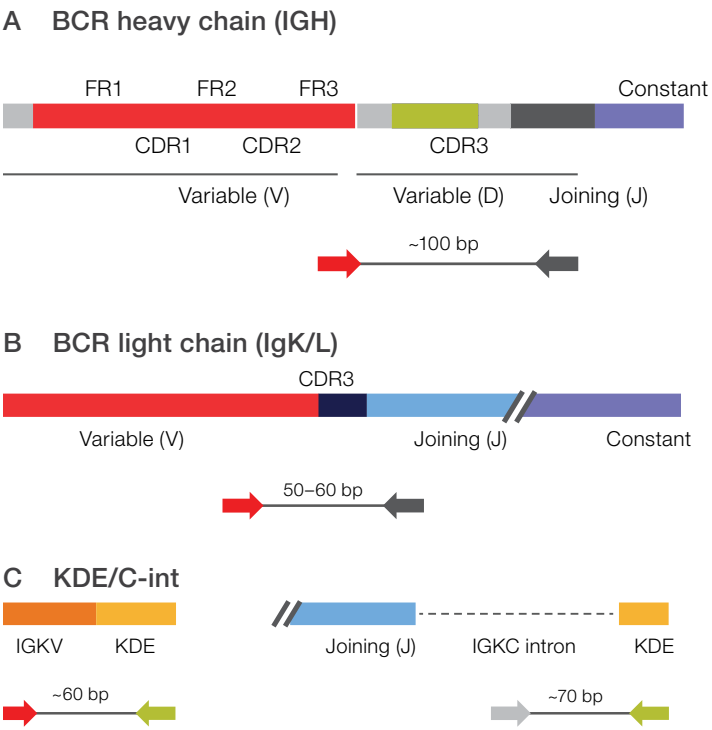
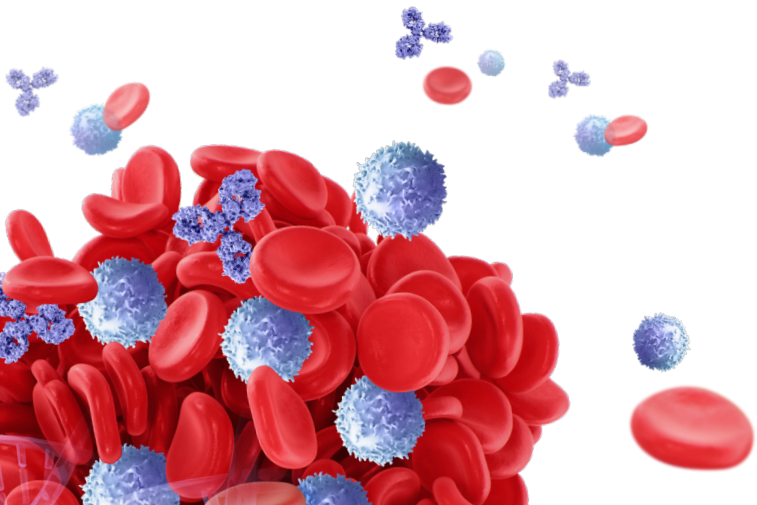


Figure 1. Oncomine BCR Pan-Clonality Assay primer design.



Oncomine TCR Pan-Clonality Assay—detect low-frequency T cell clones

The Oncomine TCR Pan-Clonality Assay specifically interrogates the CDR3 region of the T cell receptor (TCR) beta and gamma chains.

- Detect low-frequency T cell clones with sensitivity down to 10^{-6}
- Target the FR3-J regions of the TCR beta chain and TCR gamma chain with one assay

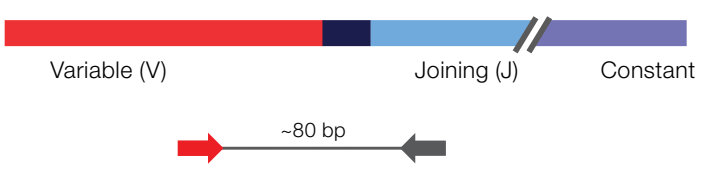


Figure 2. Oncomine TCR Pan-Clonality Assay primer design.

Somatic hypermutation research assays

Oncomine BCR IGHV Leader-J Assay—measure SHM precisely

With the Oncomine BCR IGHV Leader-J Assay, you can accurately measure the level of somatic hypermutation (SHM) in the IGHV genes with the ultralow substitution error rate of the Ion Torrent™ platform.

- Sequence from the leader to joining region of the BCR IGHV gene to assess SHM frequency
- Get appropriate coverage of the leader region, as recommended by the European Research Initiative on CLL (ERIC); these standards aid in the understanding of the biological relevance for immunogenetic analysis
- Enjoy simple and intuitive analysis using the automated capability built into the bioinformatics software

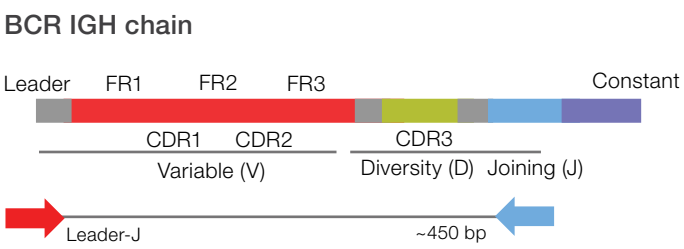


Figure 3. Oncomine BCR IGHV Leader-J Assay primer design.

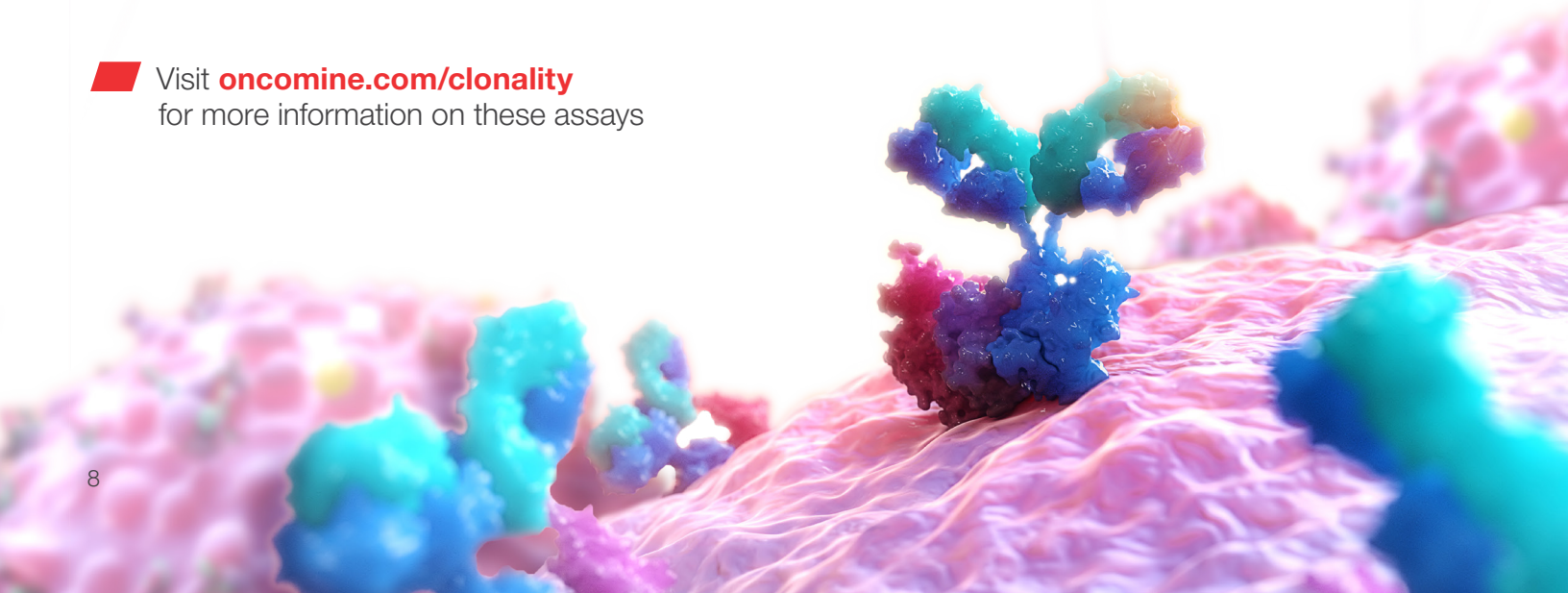
We offer a comprehensive family of immune repertoire assays to suit the needs of different laboratories. This portfolio includes a number of secondary testing assays to help increase the overall clone detection rate.

Immune repertoire assay summary

Assay	Target(s)	Nucleic acid input	Sample types	Application(s)
Oncomine BCR Pan-Clonality Assay	BCR, IGH, IGK, IGL, KDE/ C_{int}, (FR3-J)	gDNA	Whole blood; bone marrow; PBLs*; PBMCs*; sorted cells; fresh, frozen and FFPE-preserved tissue samples	Clonality, MRD detection
Oncomine BCR IGH-SR Assay	BCR IGH (FR3-J)	gDNA, RNA		
Oncomine IGH FR3(d)-J Assay	BCR IGH (FR3(d)-J)	gDNA		
Oncomine IGH FR2-J Assay	BCR IGH (FR2-J)	gDNA		
Oncomine TCR Pan-Clonality Assay	TCRB, TCRG (FR3-J)	gDNA		
Oncomine BCR IGHV Leader-J Assay	BCR IGH (Leader-J)	gDNA	Whole blood, bone marrow, PBLs, PBMCs, sorted cells	Somatic hypermutation
Oncomine BCR IGH-LR Assay	BCR IGHV (FR1-C)	Non-FFPE RNA	Whole blood, bone marrow, PBLs, PBMCs, fresh and frozen specimens	
Oncomine IGH FR1-J Assay	BCR IGH (FR1-J)	Non-FFPE RNA		

* PBLs: peripheral blood leukocytes; PBMCs: peripheral blood mononuclear cells.

Visit **oncomine.com/clonality** for more information on these assays



Software solutions

Ion Reporter Software—bioinformatics designed for accuracy and simplicity

Ion Reporter™ Software simplifies your bioinformatics analysis and enables you to get high-quality data by automatically prioritizing and annotating variants.

- **Efficient**—fast upload and access to your data
- **Secure**—protection and security features for your data, including e-signatures, audits, and records management
- **Automated**—push-button data analysis with preconfigured workflows
- **Convenient**—service, support, and software for one year, allowing unlimited data analyses from multiple Ion Torrent™ sequencers

Reporting

Customizable variant annotation and reporting tools are available.*

*Reporting solutions include Oncomine Reporter, the laboratory's own software, or other third-party software.

Are you ready to get started?

Our precision oncology consultants are ready to develop a hematology-oncology strategy that will work for your research needs.

See our solutions at **oncomine.com/heme**