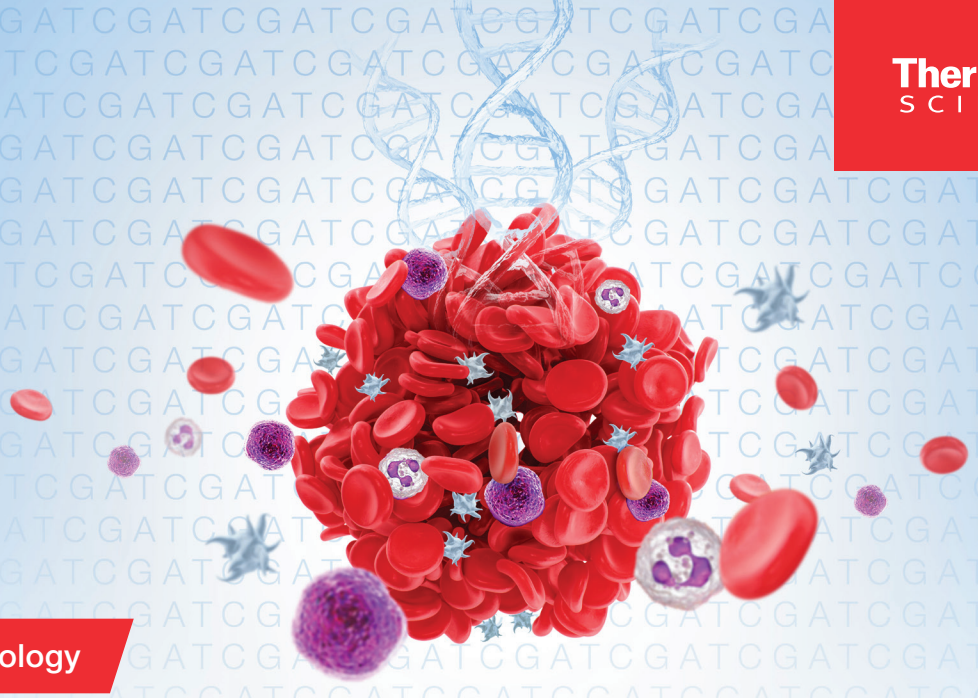

Hemato-oncology

Oncomine Myeloid Assay GX v2

More rapid, automated, and complete myeloid genomic profiling

Myeloid malignancy samples can be challenging to analyze. They are complex, heterogeneous, and have the potential to proliferate rapidly. To get meaningful genetic insights, you need a rapid and streamlined approach for profiling all key mutations.

Traditional single-analyte testing approaches can be laborious and time-consuming—especially as the list of relevant genes continues to grow. With the Ion Torrent™ Oncomine™ Myeloid Assay GX v2 on the Ion Torrent™ Genexus™ System, you can get a comprehensive profile of myeloid mutations from a single next-generation sequencing (NGS) run and results 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. Integrated bioinformatic tools allow you to seamlessly generate a variant report with annotations based on the latest evidence.

Target important biomarkers associated with major myeloid disorders

With the ability to profile both DNA and RNA targets in a single test, the Oncomine Myeloid Assay GX v2 allows you to dramatically consolidate the number of individual tests typically required for profiling a broad spectrum of mutations, including both DNA mutations and translocations detected from RNA targets.

Simultaneously interrogate 45 DNA target genes and 30 RNA fusion driver genes. This broad fusion panel allows you to sequence over 700 unique fusion transcripts. Gene content on the panel has been curated to cover relevant targets for all the major myeloid disorders—AML, MDS, MPN, CML, CMML, and JMML.

Highlights

Rapid turnaround time—from specimen to report in as little as one day

Highly automated workflow—process samples with just 20 minutes of hands-on time required

Comprehensive target coverage—simultaneously profile 45 key DNA genes and 30 fusion drivers (>700 unique fusions) relevant for the spectrum of major myeloid disorders

Trusted performance—reliably detect a range of variants, including challenging single nucleotide variants (SNVs) in homopolymer regions and important internal tandem duplications (ITDs) and partial tandem duplications (PTDs)

Integrated reporting—get annotated variants, including links to the latest relevant evidence, to help inform biological significance

* The automated end-to-end workflow will be available for RNA samples after the Total RNA Purification kits are available in approximately early 2022. The content provided herein may relate to products or workflows that have not been officially released or fully validated and is subject to change without notice.

Trusted performance for detecting key mutations

Myeloid samples frequently harbor mutations in difficult-to-sequence regions of the genome. Our assay primer design and chemistry has been carefully engineered to:

- Reliably detect all important mutations associated with myeloid malignancies
- Accurately detect SNVs in genes with long homopolymer regions like *CEBPA* and *ASXL1*
- Detect a range of insertions and deletions, even in challenging genes like *CALR*
- Identify ITDs in *FLT3* and PTDs in *KMT2A*
- Get optimal performance for challenging insertions with integrated FTL3-ITD detection software

Table 1. Oncomine Myeloid Assay GX v2 gene targets.

DNA panel: hotspot genes (28)		DNA panel: full genes (17)		RNA panel: fusion driver genes (30)			RNA panel: expression genes (5)	RNA panel: expression control genes (5)
ANKRD26	*KRAS*	*ASXL1*	*PRPF8*	*ABL1*	*HMGA2*	*NUP98*	*BAALC*	*EIF2B1*
ABL1	*MPL*	*BCOR*	*RB1*	*ALK*	*JAK2*	*NUP214*	*MECOM*	*FBXW2*
BRAF	*MYD88*	*CALR*	*RUNX1*	*BCL2*	*KMT2A*	*PDGFRA*	*MYC*	*PSMB2*
CBL	*NPM1*	*CEBPA*	*SH2B3*	*BRAF*	(*MLL* PDTs)	*PDGFRB*	*SMC1A*	*PUM1*
CSF3R	*NRAS*	*ETV6*	*STAG2*	*CCND1*	*MECOM*	*RARA*	*WT1*	*TRIM27*
DDX41	*PPM1D*	*EZH2*	*TET2*	*CREBBP*	*MET*	*RBM15*		
DNMT3A	*PTPN11*	*IKZF1*	*TP53*	*EGFR*	*MLLT10*	*RUNX1*		
FLT3 (ITD,	*SMC1A*	*NF1*	*ZRSR*	*ETV6*	*MLLT3*	*TCF3*		
TKD)	*SMC3*	*PHF6*		*FGFR1*	*MYBL1*	*TFE3*		
GATA2	*SETBP1*			*FGFR2*	*MYH11*			
HRAS	*SF3B1*			*FUS*	*NTRK3*			
IDH1	*SRSF2*							
IDH2	*U2AF1*							
JAK2	*WT1*							
KIT								

Highly automated NGS workflow—from specimen to report

Specimen	Genexus System	Oncomine Reporter
✓ Whole blood ✓ Peripheral blood leukocytes (PBLs) ✓ Bone marrow	✓ Automated specimen-to-report workflow, including nucleic acid extraction and quantification, library preparation, sequencing, and variant calling	✓ Annotated variant report links biomarkers to relevant evidence from public data sources

Start with any common myeloid specimen type. From there, the Genexus System integrates and automates the entire workflow. With only 20 minutes of hands-on time required, your lab can be more efficient and free up staff's time to focus on other applications.

Each lane on the Ion Torrent™ GX5™ Chip can accommodate up to eight samples in a sequencing run. The four-lane chip and reagents are stable on the instrument for two weeks, giving you the flexibility to batch samples across multiple runs without having to waste unused sequencing capacity.

Onboard, integrated analysis provides robust variant calling and reporting without the need for an external server. The simplified user experience helps minimize the learning curve and avoid human error. The Ion Torrent™ Oncomine™ Reporter is a curated knowledge-base and reporting software that links variants to relevant evidence and enables custom reporting. These tools help simplify the bioinformatics workflow and enable you to focus on finding the biological meaning of your data.

Specifications

Gene targets	28 hotspot genes (DNA), 17 full genes (DNA), 30 fusions drivers (RNA), >700 unique fusions, 5 expression genes, 5 expression controls
Variants	SNVs, insertions, deletions, ITDs, PTDs, gene fusions
Input	20 ng DNA, 10 ng RNA
Turnaround time	22 hours for 8 samples (automated library prep, sequencing, reporting)
	27 hours for 8 samples (automated extraction, purification, library prep, sequencing, reporting)
Throughput	8 DNA and 8 RNA samples per lane, per run
	32 DNA and RNA samples per chip
Coverage	≥99%
Sensitivity	≥95%

We offer different assay configurations to meet your lab's unique needs. Profile DNA and RNA targets simultaneously or have the option to profile each independently.

Ordering information

Product	Cat. No.
Oncomine Myeloid Assay GX v2	A50694
Oncomine Myeloid DNA Assay GX v2	A50753
Oncomine Myeloid RNA Assay GX v2	A50754

Learn more about the Oncomine Myeloid Assay GX v2 at **oncomine.com/myleoid**