Hemato-oncology

Oncomine Myeloid MRD Assays (RUO)

A universal assay for efficient, sensitive variant detection

Background

Measurable residual disease (MRD) in myeloid neoplasms is an area of intense research. Ongoing studies are highlighting the value of MRD for determining risk profiles based on mutational clearance and potential therapeutic options for MRD-positive cases. Next-generation sequencing (NGS) technology is a promising method for MRD detection because of its ability to profile multiple mutations simultaneously with high sensitivity. This approach provides a universal assay for investigating all common mutations across a range of myeloid neoplasm samples.

Assay overview

The new Ion Torrent™ Oncomine™ Myeloid MRD Assays (RUO) on the Ion GeneStudio™ S5 System offer a complete NGS solution for myeloid MRD detection. Error-correcting NGS, based on Ion AmpliSeq™ HD technology, enables variant detection with sensitivity as low as 0.05% allele frequency.

MRD panels

A DNA and an RNA assay are available to cover a wide range of myeloid MRD targets, including key single-nucleotide variants (SNVs), insertions and deletions (indels), tandem duplications, and key gene fusions. Detect important biomarkers like *NPM1*, *PML-RARA*, *IDH1/2*, *BCR-ABL1*, and *FLT3* (ITD and TKD). The carefully curated targets on the panel are relevant for all major types of myeloid neoplasms, including acute myeloid leukemias (AML), myelodysplastic syndromes (MDS), and myeloproliferative neoplasms (MPN) samples.

Highlights of the Oncomine Myeloid MRD Assays (RUO):

Comprehensive gene panels
DNA and RNA targets relevant for myeloid MRD (SNVs, indels, fusions, tandem duplications)

High sensitivity
Variant detection down to 0.05% allele frequency

Fast and simple workflow
Results in 2–3 days with ~2 hours of hands-on time required

Optional chimerism analysis
Highly sensitive measurement of donor–recipient mixtures

Integrated analysis and reporting
Analytically validated informatics pipeline with annotation and integrated reporting

Content summary

DNA assay

- 33 genes, including 2 full genes and *FLT3*-ITDs
- 1,255 hotspots
- Optional 22-amplicon micro-haplotype panel for chimerism analysis

RNA assay

- 42 fusion driver genes
- 990 unique fusions
- 6 genes with exon splicing variants
- 5 expression control genes

Table 1. Gene targets of the Oncomine Myeloid MRD Assay (RUO).

DNA assay			RNA assay					
DNA gene targets			Fusion driver genes				Expression controls	Exon splicing variants
ABL1	*GATA2*	*PTPN11*	*ABL1*	*FUS*	*MYBL1*	*RARA*	*ABL1*	*KMT2A*
ASXL1	*IDH1*	*RUNX1*	*ABL2*	*GLIS2*	*MYH11*	*RARB*	*GUSB*	*RUNX1*
BCOR	*IDH2*	*SETBP1*	*ALK*	*HMGA2*	*NOTCH1*	*RARG*	*PSMB2*	*NOTCH1*
BRAF	*JAK2*	*SF3B1*	*BCL2*	*JAK2*	*NTRK1*	*RET*	*PUM1*	*ETV6*
CALR	*KIT*	*SH2B3*	*BRAF*	*KAT6A (MOZ)*	*NTRK2*	*RUNX1*	*TRIM27*	*IKZF1*
CBL	*KRAS*	*SRSF2*	*CCND1*	*KAT6B*	*NTRK3*	*TAL1*		*NTRK1*
*CEBPA**	*MPL*	*STAG2*	*CREBBP*	*KMT2A**	*NUP214*	*TCF3*		
CSF3R	*MYD88*	*TET2*	*CSF1R*	*KMT2A-PTD*	*NUP98*	*TCF4*		
DNMT3A	*NPM1*	*TP53**	*EGFR*	*MECOM*	*PAX5*	*TFE3*		
EZH2	*NRAS*	*U2AF1*	*ETV6*	*MLLT10*	*PDGFRA*	*ZNF384*		
*FLT3***	*PHF6*	*WT1*	*FGFR1*	*MRTFA (MLK1)*	*PDGFRB*			

* Full gene coverage.

** Exon 14 and 15, includes *FLT3*-ITDs and TKD mutations.

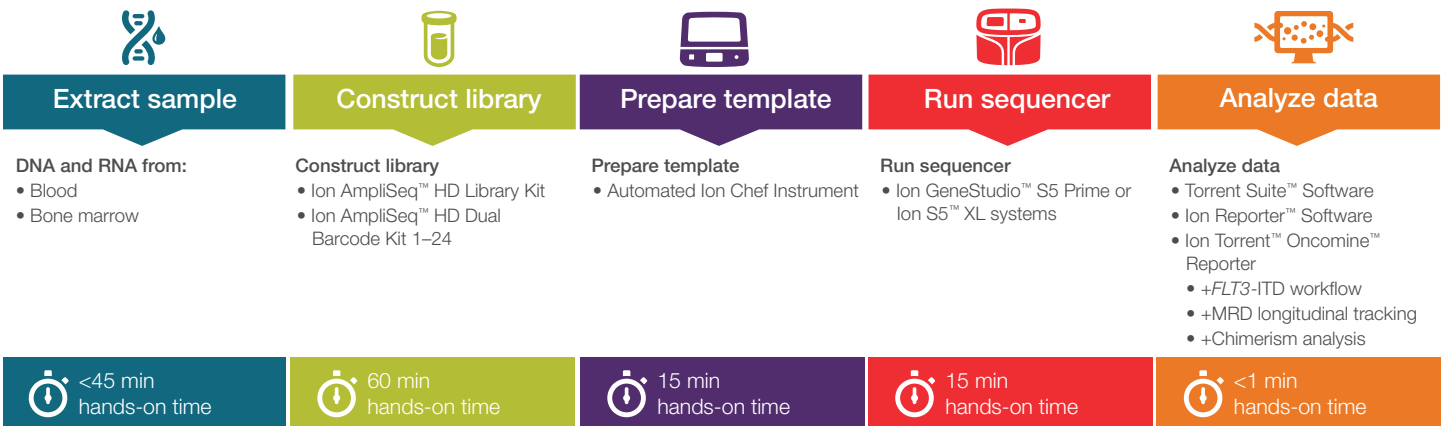
Micro-haplotyping panel

Customers can also add an optional 22-amplicon DNA panel for chimerism analysis in post–allogeneic stem cell transplantation (allo-HSCT) research samples. This innovative NGS technique measures the ratio of donor/recipient DNA down to 0.2% allele frequency. Unlike traditional methods that rely on qualitative analysis, NGS provides digital quantification of allele mixtures to identify low-frequency, disease-associated markers with high sensitivity. With this approach, the proportion of potentially malignant cells can be assessed even in absence of known mutations.

Workflow

The Oncomine Myeloid MRD Assays (RUO) include a fully integrated workflow based on the Ion GeneStudio S5 System. The entire process can be completed in 2–3 days with roughly 2 hours of hands-on time.

Start with DNA or RNA extracted from blood or bone marrow. Easily prepare the sequencing library with less than an hour of hands-on time using Ion AmpliSeq™ HD kits. This method uses simple, PCR-based library preparation. From there, the Ion Chef™ Instrument performs automated templating on the chip before sequencing on the Ion GeneStudio S5 System. Integrated analysis and reporting simplify the interpretation of results.



Informatics and reporting

The solution includes an integrated complete analysis pipeline that allows labs to easily analyze samples without needing deep informatics expertise typically required for other assays. The output can be automatically imported into Oncomine Reporter for variant annotation based on the most relevant evidence from publicly available data sources, including research information on the latest labels, trials, and guidelines.

Specifications

	Details
Sensitivity	0.1–0.05% limit of detection (LOD)
Sample type	gDNA, or total RNA from blood and bone marrow
Sample input	10 ng RNA (1 pool) 120 ng DNA (60 ng in Pool 1, 60 ng in Pool 2)
Samples per Ion™ S5 chip	S540: 4 S550: 6 (Requires Ion GeneStudio S5 Prime or Ion S5 XL systems)
Turnaround time	Day 1: Library prep and quantitation Day 2: Templating Day 3: Sequencing and data analysis

Ordering information

Product	Reaction size	Samples per kit	Cat. No.
Oncomine Myeloid MRD DNA Assay (RUO)	24	24 DNA	A53838
Oncomine Myeloid MRD RNA Assay (RUO)	24	24 RNA	A53839

Learn more at **oncomine.com/myeloid-mrd**