MyMRD®

Technical Information

Single MRD Test - Many Advantages

BE CONFIDENT

Accurate results with 0.5% sensitivity and >98% coverage of most coding targets*

INFORM CLINICAL DECISIONS

Actionable results to optimize treatment and track clonal evolution

ACCELERATE DRUG APPROVALS

Surrogate marker for overall survival in clinical trials

Clinical Significance

Measurable residual disease (MRD) detection has proven to be a valuable in the clinical management of patients with myeloid malignances. Unlike traditional methods, next-generation sequencing (NGS) hotspot gene panels can characterize the heterogeneity of disease and detect low level variant mutations with unprecedented accuracy using a single blood or bone marrow sample. The MyMRD Gene Panel has been shown to detect at least 1 driver mutation in more than 90% of myeloid diseases. Once a mutation or "clone" is identified, the same test can be used to monitor disease evolution.

Sophisticated bioinformatics analyses are then exploited to interpret and annotate findings implicated in causation, prognosis, and recurrence. Increasingly, gene panels are being adopted by pharma to accelerate drug approvals and by oncologists to comprehensively monitor patients in remission.

Indications for Testing

- Acute Myeloid leukemia (AML)
- Myelodysplastic Syndrome (MDS)
- Myeloproliferative Neoplasms (MPN)
- Chronic Myeloid Leukemia (CML)
- Chronic Myelomonocytic Leukemia (CMML)
- Juvenile Myelomonocytic Leukemia (JMML)

NGS Gene Panel

Turnaround Time	Interpretation	Specimen Requirements	Storage & Shipping Conditions
7-10 business days	An interpretive report will be issued indicating the likely pathogenic variants with a description of biological and clinical significance.	3 mL of peripheral blood in Heparin or EDTA **OR** 1 mL of bone marrow in Heparin or EDTA **OR** 1 µg of purified, high quality genomic DNA	Ambient or cool (do not freeze) Room temperature up to 72 hours 4˚C up to 7 days

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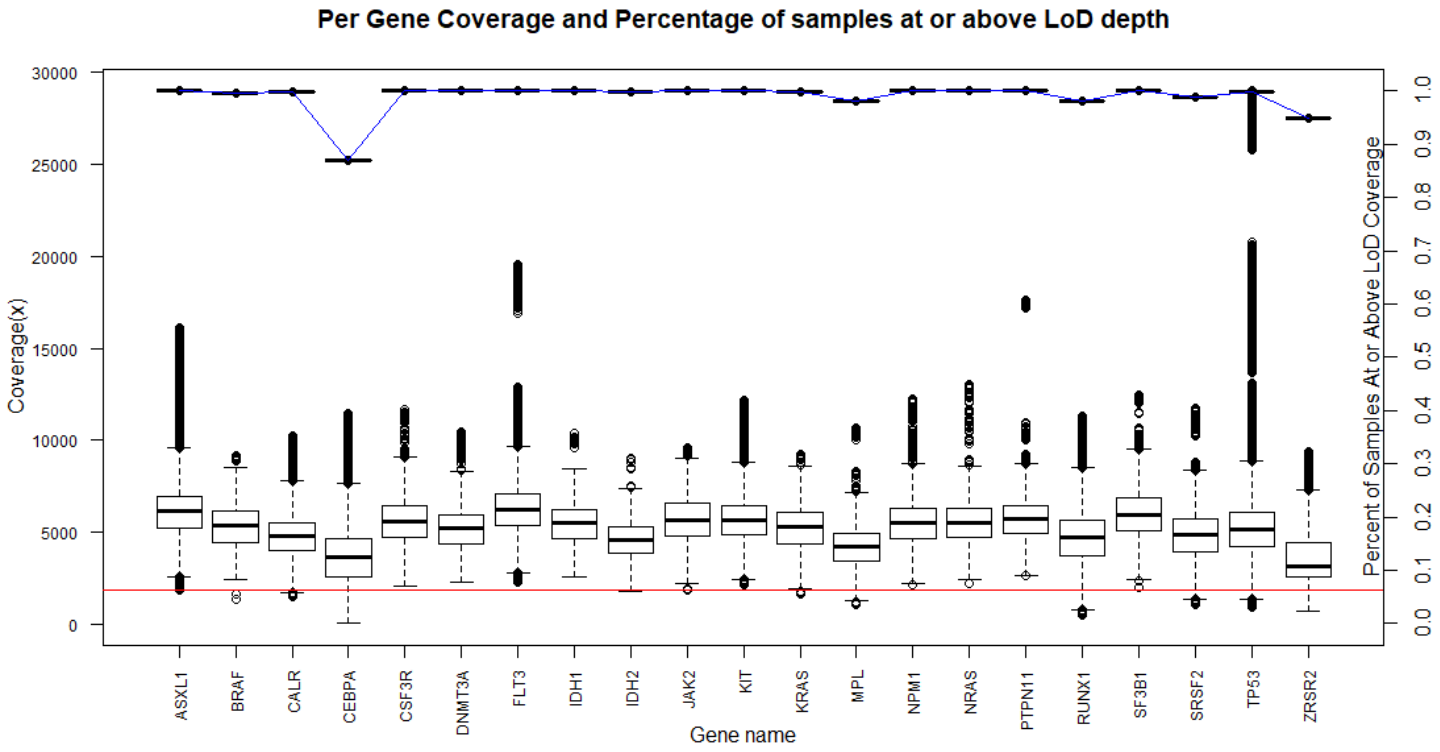
Clinical Performance

The deep sequencing of this hotspot myeloid panel confidently and reproducibly provides $5x10^{-3}$ sensitivity for 98% of coding targets* and $2.5x10^{-2}$ for structural variants, with additional sensitivity achievable for specific targets of interest. This sensitivity is achieved by coupling enhanced depth of coverage and long read lengths with robust MyInformatics software.

MyInformatics® Software

Actionable annotated results are generated using proprietary MyInformatics bioinformatics software. Mutations, including single nucleotide variants (SNVs), insertions and deletions (indels), and structural variants are detected with unparalleled precision. Variants are annotated in an interpretive report following the Clinical Oncology, College of American Pathologists, and American College of Medical Genetics and Genomics recommendations.



MyMRD Gene Panel

SNV and Indel Exon Targets in 23 Genes					Structural Variants
ASXL1	*BRAF*	*CALR*	*CEBPA*	*CSF3R*	*CBFB-MYH11*
DNMT3A	*FLT3*	*IDH1*	*IDH2*	*JAK2*	*KMT2A*
KIT	*KMT2A*	*KRAS*	*MPL*	*MYH11*	*RUNX1-RUNX1T1*
NPM1	*NRAS*	*PTPN11*	*RUNX1*	*SF3B1*	-
SRSF2	*TP53*	*ZRSR2*	*ZRSR2*	-	-

*Due to the high GC content of the *CEBPA* coding sequence, the LOD of this gene is limited to 1.0%.

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To inquire about availability please email businessdevelopment@invivoscribe.com.