

ImmunoID NeXT™

Biomarker Discovery Solutions for Lymphoma and Multiple Myeloma



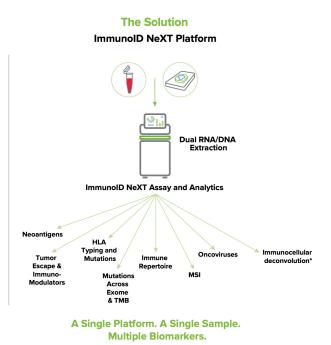
Comprehensive Characterization of Genetic Events With Combinatorial DNA and RNA Profiling

It Starts with a Superior Assay

Lymphoma and multiple myeloma account for more than 65 percent of newly diagnosed hematological cancer cases¹. The genetic landscape of these lymphoid malignancies is complex, and these diseases are further categorized into many types and subtypes based on the presence of characteristic genetic alterations. The spectrum of mutations observed in these malignancies is highly variable ranging from translocations, insertions and deletions (indels), single nucleotide variations (SNVs), and copy number alterations (CNAs). Although advances in molecular biology and next generation sequencing have helped discover many novel pathogenic alterations in these cancers, the limited quantity and type of banked samples (such as FFPE and FNA) still pose a huge challenge for conventional assays to comprehensively profile these cancers, thereby limiting the scope of biomarker discovery.

The ImmunoID NeXT Platform® offers customers an optimized assay by combining highly-sensitive, exome-scale DNA and RNA sequencing, along with fully integrated advanced analytics to provide a multidimensional view of the underlying genetic landscape of cancer. ImmunoID NeXT employs a sample-sparing approach, configured to work with limited and difficult sample types to perform dual DNA and RNA extraction from the same sample, enabling simultaneous detection of a wide spectrum of genomic alterations. Additionally, ImmunoID NeXT optimizes both genomic footprint and limits of detection with a proprietary augmentation method, enhancing the potential for the discovery of biomarkers and facilitating the characterization of otherwise seemingly identical cancers into distinct disease types with distinguishable patterns of molecular alterations.

The Problem Traditional Process Requires Multiple Samples and Assay Techniques Multiple Sections Sent to Multiple Vendors Multiple Assays and Analytics **HLA Typing** Mutational Burden Repertoire Array X Limited sample often leads to X Time-to-result may be extended trade-offs and incomplete datasets X May not be future-proof (complicates X Data integration and interpretation retrospective analysis) is complex





*In Development

Explore An Expansive Set of Biomarkers to Advance Therapeutic Development

ImmunoID NeXT: Lymphoma and Multiple Myeloma

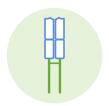
Extensive mutational profiling including **SNVs**, **indels**, **fusion-events**, **exome-wide copy number changes** for discovering **co-occurring alterations** unique to disease types and subtypes.



Pathways

Mutational Status

- MAPK, NOTCH, JAK/STAT, PI3K/AKT Dysregulations
- DNA Damage Response (DDR)
- Cell Cycle Regulators
- Epigenetic Modulators



Immune Repertoire

RepertoireID

TCR Clonotypes



Signatures

Novel Gene Signatures

- Fusions
- Gene, Transcript and Variant Level Expression
- Genomic Instability Markers



Chromosomal Aberrations

Amplifications

• MYC, BCL2, PIK3CA

Deletions

• PTEN, TP53 (del17p), CDKN2A



HLA

HLA Class I & II Genotyping

- HLA LOH
- HLA & B2M somatic mutations



The ImmunoID NeXT™ Assay Features Include:

- Augmented exome-wide coverage: Proprietary Accuracy and Content Enhanced (ACE) technology augments coverage of difficult-to-sequence regions (e.g., areas of high-GC content) across all >20,000 genes
- **Deep sequencing**: ~300X mean whole exome sequencing coverage and 200M total reads of RNA sequencing of the tumor specimen
- 1000X boosted coverage for 247 cancer-related genes: Enhanced sensitivity in profiling recurrently mutated genes and pathways in lymphoid malignancies including BTK, MYD88, BCL6, BCL2, EZH2, PTEN, TP53, MYC, KRAS, NRAS, BRAF, FGFR3, RB1, ATM, ATR, CHEK1/2, CCND1/2/3, CDKN1A/1B, CDKN2A/2B, IGF-1R, KDM6A, CREBBP, ARID1A, ALK, NOTCH1/2, JAK/STAT and PI3K-AKT-mTOR pathways
- Fusion detection: Optimized pipeline for enhanced fusion detection from RNA analysis
- Expression signature: Accurate gene, transcript and variant level expression profiling
- CNA profiling: Detection of copy number alterations across the whole exome
- TCR repertoire profiling: Characterization of TCR clones in the repertoire offers potential utility as a predictive biomarker of response to therapies
- HLA typing and LOH detection: Optimized HLA typing tool for accurately genotyping Class I and II loci
- Tumor mutational burden (TMB) evaluation: Accurate quantification of exome-based TMB value in tumor samples
- Neoantigen prediction: Accurate prediction of immunogenic patient specific neoantigens

In recent years, approvals for small molecule inhibitors such as Idelalisib (PI3K-ð) and Ibrutinib (BTK) have expanded the landscape of available drugs for lymphomas². Similarly, a wide spectrum of therapeutic options including immunomodulatory drugs, proteasome inhibitors and monoclonal antibodies have been approved for treating multiple myeloma. Moreover, a plethora of new agents are currently in clinical trials, increasing the possibility of developing selective combination regimens to improve therapeutic efficacy in these cancers³.

Identification of predictive biomarkers becomes crucial in order to support streamlined drug-development efforts and facilitate successful patient stratification for the right combination drug regimens. ImmunoID NeXT offers a complete biomarker solution with augmented exome-wide genomic footprint coverage to identify a wide spectrum of genetic aberrations, thereby allowing sub-classification and characterization of distinct therapeutically meaningful disease subgroups. ImmunoID NeXT, with its future-proof design, is an ideal comprehensive alternative to small pre-selected targeted panels that lack adequate genomic footprint coverage, and provides the opportunity to discover multiple biomarkers using a single platform.

References

- 1. Howlader N et al. SEER Cancer Statistics Review, 1975-2017, National Cancer Institute
- 2. Anas Younes et al. The landscape of new drugs in lymphoma, Nature Reviews Clinical Oncology. 2017
- Salomon Manier et al. Genomic complexity of multiple myeloma and its clinical implications, Nature Reviews Clinical Oncology. 2017



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