NuGEN Technologies

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Accelerating genomics with advanced sample preparation solutions

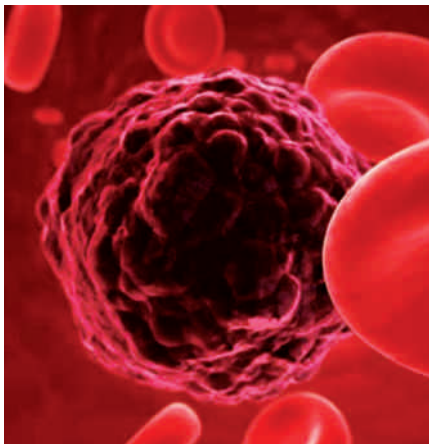
NuGEN Technologies provides scientists and clinicians with innovative and reliable sample-preparation technologies for targeted genomic analysis and diagnostics.

With the advent of fast, high-capacity genomic-sequencing technologies, scientists are gaining new insights into the fundamental mechanisms of disease, enabling doctors to analyze a patient's genetic makeup for improved diagnosis and personalized treatment. But while next-generation sequencing (NGS) platforms are having a major impact on clinical research and diagnostic testing, useful insights can only be gained if samples are prepared for analysis in a reliable, unbiased and reproducible manner.

NuGEN Technologies offers more than 100 sample-preparation products that allow laboratories and clinics around the world to efficiently target and obtain useful sequencing data from a broad range of samples, including those that are limited in quantity, degraded or otherwise challenging to process.

In oncology, an understanding of the molecular changes that drive an individual tumor can lead to clearer diagnosis, treatment and even monitoring for recurrence. Yet at each step in patient care, tissue availability may be very limited. NuGEN's SPIA (single-primer isothermal amplification) technology solves this problem by using high-efficiency amplification to enable expression analysis of very low-level nucleic acid samples on both microarray and NGS platforms. With SPIA, efficient sample processing from fine needle aspirate (FNA) samples is possible, in some cases eliminating the need for more invasive biopsy procedures. SPIA also enables the analysis of other limited and/or compromised biological samples, including laser-captured microdissections, sorted cells, embryonic structures and formalin-fixed paraffin-embedded (FFPE) samples. SPIA is the core technology used in the Ovation Pico WTA System for microarrays and the Ovation RNA-Seq System V2 for NGS.

Blood samples, a potentially useful source of gene-expression data in clinical trials, pose a challenge because of the prevalence of hemoglobin RNA. Insert Dependent Adaptor Cleavage (InDA-C) is a NuGEN technology that uses a targeted approach to deplete unwanted high-abundance transcripts during sequencing library construction. InDA-C substantially reduces the number of sequencing reads that are derived from the high-abundance RNA while leaving the original RNA population unperturbed, thereby reducing the potential for the introduction of bias into the results. This technology also ensures more efficient use of sequencing resources by effectively depleting ribosomal RNA reads when total RNA input is used to prepare sequencing libraries. InDA-C is the core technology used in the Ovation Human Blood RNA-Seq System.



Microscopic image of a circulating tumor cell.

SPET (single-primer enrichment technology) another innovative NuGEN technology, maximizes the information yield from NGS with a rapid and efficient sample-preparation workflow. SPET is a target-enrichment tool that allows for the simultaneous detection of single-nucleotide polymorphisms (SNPs), copy-numbers variants (CNVs) and insertions or deletions. Until recently, CNV and sequence analysis have required completely different analytical platforms and sample preparation to elucidate information for these three types of genetic variation. SPET does so in a single assay, conserving patient samples and making more efficient use of sequencing resources. SPET is the core technology used in the Ovation Cancer Panel 2.0 Target Enrichment System.

SPET can also be used to identify gene-fusion events and sequence variants in an RNA sample. The SPET technology for targeted RNA sequencing is flexible enough to target any gene in any organism for gene-fusion detection and gene-expression analysis. This will be an important contribution to RNA-seq–based cancer diagnostic and prognostic tests.

Real-world applications

Reproducible results from whole blood

PreAnalytiX and RUCDR Infinite Biologics partnered with NuGEN to develop and validate an end-to-end workflow for the reproducible collection and processing of whole blood for RNA-seq in clinical studies. The study team found highly reproducible results across sites, operators and equipment. "We have determined that the PreAnalytiX-NuGEN integrated workflow ensures reproducible, accurate and sensitive results in RNA-seq of whole blood," said Andrew Brooks, COO of RUCDR Infinite Biologics, who led the study. "Importantly, this integrated workflow enables gene expression from total RNA, allowing researchers to study both protein coding and regulatory transcripts from human whole blood."

Veracyte uses NuGEN's RNA-amplification and labeling technology in its microarray-based Afirma Thyroid FNA Analysis assay for the stratification of indeterminate thyroid tumors. The test greatly reduces unnecessary surgical intervention in patients and is reimbursed by Medicare and numerous other health insurers.

Sample prep for clinical cancer diagnostics

NuGEN is working with leading molecular-diagnostics companies to develop and commercialize genomic diagnostic and prognostic tests. The enabling characteristics of NuGEN's sample-preparation technologies translate well to clinical settings, in which samples are often limited and whole blood and FFPE samples are widely used. To facilitate the translation of diagnostic research into the clinic, NuGEN has established rigorous quality standards, including ISO 13485:2003 certification and California State current good manufacturing process (cGMP) licensure, making it one of the first reagent companies to meet these exacting qualifications.

NuGEN is a pioneer in developing innovative sample-preparation solutions for targeted genomic analysis. From the early days of microarray technology to present-day NGS, NuGEN has been a leader in the development and manufacture of innovative technologies that help bring the benefits of the genomic revolution to all.

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