



Asuragen Announces New Notice of Allowance from USPTO Related to the Use of a miRNA as a Normalizer for miRNA Gene Expression Analysis

AUSTIN, TX – May 24, 2011. [Asuragen, Inc.](#), a leader in the development of molecular diagnostics, announced today that it has received a Notice of Allowance from the United States Patent and Trademark Office (“USPTO”) for claims related to the use of miRNAs as normalizers in gene expression studies. Data normalization is necessary to control for sample variability that can adversely affect the accurate quantification of gene expression. Improper normalization can affect the magnitude and even the direction (up or down) of change in miRNA gene expression in diseased clinical samples, such as tumor specimens, and is critical for the development of robust and reliable research and diagnostic assays. Normalization methods currently in use have significant shortcomings, especially for analyzing small differences in miRNA expression that are biologically meaningful and can occur between diseased and normal samples.

Asuragen’s novel methods utilize endogenous miRNAs for normalization of gene expression. These studies validated the use of numerous different endogenous miRNAs for normalization with a variety of tissue and sample types. The claimed methods will be particularly useful for gene expression measurements that employ RT-qPCR, the method of choice for diagnostic assays based on differences in miRNA expression.

Asuragen has a broad IP portfolio with over 70 issued and pending patents related to miRNA including some of the earliest functional diagnostic applications for a number of key miRNAs associated with oncology diseases.

About microRNA

miRNAs are approximately 21 nucleotides long and affect gene expression by interacting with messenger RNAs. Unlike siRNAs, miRNAs are encoded in the human genome and are natural regulators of global gene expression. More than 900 miRNAs are encoded in the human genome and comprise approximately 2% of all mammalian genes. Since each miRNA appears to regulate the expression of tens to hundreds of different genes, miRNAs can function as “master-switches,” regulating and coordinating multiple cellular pathways and processes. By coordinating the expression of multiple genes, miRNAs are responsible for guiding proper embryonic development, and regulating processes involved in immunity, inflammation, as well as cellular growth and proliferation. Misregulation of miRNAs appears to play a fundamental role in many cancers and unique microRNA profiles have been identified that are useful for diagnosis of certain cancer types.

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About Asuragen

Asuragen is a fully integrated diagnostic development company and pharmaceutical services provider. The Company's diagnostic product portfolio consists of the first-ever validated microRNA diagnostic assay for pancreatic cancer, quantitative RNA tests for leukemia gene translocations, innovative genetic testing solutions for the fragile X mental retardation (FMR1) gene, Signature® Oncology products for the qualitative detection of gene translocations and mutations in a variety of hematological and solid tumors, RNA stabilization technologies, and industry-leading controls and standards engineered using its patented Armored RNA® technology. Asuragen is empowered with a high level of scientific expertise and assay development capabilities, CLIA and GLP testing services, and an established cGMP manufacturing facility, which allow it to span the spectrum of discovery, testing, production and commercialization. For more information, visit www.asuragen.com.

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