



## PerkinElmer Secures FDA 510K Clearance for Newborn Screening Platform

WALTHAM, Mass., Nov 03, 2009 (BUSINESS WIRE) --PerkinElmer, Inc., a global leader focused on the health and safety of people and the environment, today announced that the Company has received 510K clearance from the U.S. Food and Drug Administration for its GSP™ Genetic Screening Processor, which is used by public health laboratories worldwide as part of newborn screening programs.

In newborn screening programs, infants are tested for a range of genetic, metabolic or hematologic disorders. When identified within the first few days of life, these disorders are often easily managed, but if left untreated, could lead to serious illness or even death. The testing process begins with the collection of a few drops of blood from a heel prick.

The GSP™ system makes it much easier for labs to analyze newborn blood samples by providing the capability to run more than one test at once on very small samples. The GSP™ is an automated platform able to quantitatively and qualitatively analyze blood spot samples for irregularities associated with metabolic diseases that when detected early, can often be easily treated. With multi-analyte analysis capability and a two-fold capacity over prior systems, the GSP system delivers increased efficiency and flexibility over other methods, while reducing the risk of errors associated with manual processing of samples.

The GSP™ analyzer eliminates the need to analyze all samples in batches, permitting specimens to be processed as they arrive in the laboratory. This flexibility improves response time for delivering results to physicians and parents and eases the challenge of sample workflow management. Multi-analyte capability permits analysis for several analytes simultaneously, preserving the small sample volume for a wider range of analysis. The GSP™ Neonatal TSH assay is the first assay to receive FDA clearance for the GSP™ instrument. Several additional newborn screening assays are in development.

"FDA approval of PerkinElmer's GSP™ system provides laboratories in the U.S. with a next-generation system that can help address the staffing and workflow needs of today's demanding environment," said Ann-Christine Sundell, president, Genetic Screening, PerkinElmer. "This achievement reflects our ongoing commitment, as the global leader in newborn screening, to improving medical outcomes by developing the highest quality newborn screening solutions."

The GSP™ performs each stage of the assay process, from the retrieval of the sample plate to sample measurement, and reporting of results in a single platform. All-inclusive technology allows operational efficiency by accelerating workflows and reducing hands-on time, which, when combined with the availability of barcoding, reduces the risks of human error.

The GSP™ analyzer is designed to be flexible and can be seamlessly integrated into a range of lab operations. The processor will allow for both multi-analyte screening as well as the ability to run traditional immunoassays or enzymatic-assays, thus accommodating varying workflows. Other design features that address common laboratory challenges include the ability to continuously load samples, the refrigeration of onboard reagents, and the integration of direct access to water and waste lines to streamline processes and dedicated software.

For more information please visit <http://teamsite.porternovelli.com/sites/jjprd/default.aspx>.

About PerkinElmer, Inc.

PerkinElmer, Inc. is a global leader focused on improving the health and safety of people and the environment. The Company reported revenue of approximately \$2 billion in 2008, has around 8,500 employees serving customers in more than 150 countries, and is a component of the S&P 500 Index. Additional information is available through [www.perkinelmer.com](http://www.perkinelmer.com) or 1-877-PKI-NYSE.

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