



PerkinElmer Receives FDA Clearance for NeoBase™ 2 Non-Derivatized Tandem Mass Spectrometry Kit

October 1, 2018

In vitro diagnostic solution tests newborn babies for a variety of metabolic disorders with a single dried blood spot card

WHAT: [PerkinElmer, Inc.](#), a global leader committed to innovating for a healthier world, today announced that its [NeoBase™ 2 Non-Derivatized MSMS Kit](#) has received 510(k) clearance from the U.S. Food & Drug Administration (FDA).

Used with a tandem mass spectrometer, this in vitro diagnostic kit is intended for the quantitative measurement and evaluation of traditionally-screened amino acids and acylcarnitines, as well as succinylacetone, free carnitine, nucleoside and lysophospholipid concentrations.

HOW IT WORKS: The NeoBase 2 kit measures up to 51 analytes, including markers for screening of X-linked adrenoleukodystrophy (X-ALD) and adenosine deaminase severe combined immunodeficiency (ADA-SCID). Currently, it is the only market solution that offers testing for succinylacetone from a dried blood spot punch with a single extraction and incubation step.

A derivatized assay typically requires 12 steps, but the NeoBase 2 kit enables labs to use a simple three-step assay workflow to screen for more disorders in less time, using a newborn heel prick blood sample. PerkinElmer's [Specimen Gate® Software](#), which includes database functionality, further increases lab efficiency by storing, managing, reviewing and reporting results.

WHY: "Earlier detection can lead to faster treatment of patients, and this is especially critical for the millions of babies around the world. Laboratories therefore face increasing pressure to accurately detect disorders faster—and need a solution that will expand their screening capabilities and reduce false positive rates, without adding extra equipment or expending resources," said Naren Bhat, General Manager, Mass Spectrometry, PerkinElmer. "PerkinElmer's FDA-cleared NeoBase 2 kit offers shorter extraction time, incubation time and run time, to help laboratories detect potential health risks sooner."

MORE: PerkinElmer currently serves prenatal and newborn screening customers in more than 100 countries worldwide. Its customers have screened more than 600 million babies throughout the world for life-threatening diseases: screening 39 million babies annually around the world, helping to save more than 70 babies per day (one baby every 20 minutes).

For additional information on NeoBase 2 MSMS kit and other PerkinElmer newborn screening solutions, please visit: newbornscreening.perkinelmer.com/.

ABOUT PERKINELMER:

PerkinElmer, Inc. is a global leader focused on innovating for a healthier world. The Company reported revenue of approximately \$2.3 billion in 2017, has about 11,000 employees serving customers in more than 150 countries, and is a component of the S&P 500 Index. Additional information is available through 1-877-PKI-NYSE, or at www.perkinelmer.com.

Media Contact:

Brian Willinsky
brian.willinsky@perkinelmer.com
+1-781-663-5728