PerkinElmer EONIS Screening Test Receives CE-IVD Clearance

September 30, 2020

RT-PCR Newborn Screening Assay for SMA, SCID and XLA to be Integrated into Company’s Sample-to-Result Workflow

WALTHAM, Mass. – September 30, 2020 – PerkinElmer, Inc., a global leader committed to innovating for a healthier world, today announced that the Company’s EONISTM screening assay for newborns that simultaneously tests for SMA (spinal muscular atrophy), SCID (severe combined immunodeficiency) and XLA (X-linked agammaglobulinemia) has received CE-IVD approval. This IVD RT-PCR assay integrates into PerkinElmer’s entire newborn screening workflow to provide labs with a complete, single source solution encompassing everything from sample to solution.

SMA is one of the most common lethal recessive genetic conditions and is associated with significant motor disability, respiratory issues and nutritional compromise. SCID, known more commonly as “Bubble Boy” disease, is a rare condition, caused by a severe defect in the immune system that makes it difficult or impossible to fight off infections. XLA, most common in males, is a rare genetic disorder that affects the body’s ability to fight infection. All three diseases can be fatal if not detected at birth before symptoms appear, making early screening imperative to identify affected children so that the proper care can be conducted.

The design of the EONIS assay enables automation with JANUS Liquid Handlers to further streamline the workflow of high-throughput laboratories without compromising the sample traceability from punch to result. The traceable dried blood spot workflow consists of five main elements to detect SMA, SCID and XLA: sample collection, punching, DNA extraction, amplification and data analysis utilizing dedicated analysis software.

“The global availability of this CE-marked assay for SMA, SCID and XLA will have a profound impact. It will help save lives and dramatically improve clinical outcomes for children by ensuring treatment can be given earlier to those who need it,” said Petra Furu, GM, Reproductive Health, PerkinElmer. “The integration of this assay with our complete workflow solution is a prime example of how PerkinElmer is providing laboratories with the innovative tools needed to run a reliable, and yet, cost-effective screening program.”

PerkinElmer’s comprehensive newborn screening portfolio includes tests for more than 50 conditions known to have positive outcomes when detection and diagnosis occur early with newborn screening. To learn more about PerkinElmer’s newborn screening platforms, please visit newbornscreening.perkinelmer.com.

About PerkinElmer

PerkinElmer enables scientists, researchers, and clinicians to address their most critical challenges across science and healthcare. With a mission focused on innovating for a healthier world, we deliver unique solutions to serve the diagnostics, life sciences, food, and applied markets. We strategically partner with customers to enable earlier and more accurate insights supported by deep market knowledge and technical expertise. Our dedicated team of about 13,000 employees worldwide is passionate about helping customers work to create healthier families, improve the quality of life, and sustain the wellbeing and longevity of people globally. The Company reported revenue of approximately $2.9 billion in 2019, serves customers in 190 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.

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