



# PerkinElmer Announces its EONIS SCID-SMA Kit is First to Receive Marketing Authorization by U.S. FDA for SMA Screening in Newborns

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Building on its contributions to newborn screening globally, PerkinElmer's latest FDA authorized assay enables the simultaneous detection of SMA and SCID

WALTHAM, Mass.--(BUSINESS WIRE)-- **PerkinElmer Inc.** (NYSE: PKI), a global leader committed to innovating for a healthier world, today announced that the U.S. Food and Drug Administration (FDA) has authorized the marketing of the EONIS™ SCID-SMA assay kit for in vitro diagnostic (IVD) use by certified laboratories for the simultaneous detection of spinal muscular atrophy (SMA) and severe combined immunodeficiency (SCID) in newborns. This is the first FDA authorized assay for SMA screening in newborns in the United States and is part of the Company's broader **EONIS™ Platform**.

SMA is a leading genetic cause of infant death and is characterized by muscle weakness and atrophy resulting from progressive degeneration and loss of the lower motor neurons in the spinal cord and the brain stem nuclei. SCID, which is a group of rare inherited disorders characterized by the absence of both humoral and cellular immunity, can also lead to life-threatening health complications if untreated. Early detection and intervention are critical for newborns affected by either condition.

"For nearly three decades, PerkinElmer has delivered innovative solutions to laboratories and clinicians worldwide that help diagnose newborns with rare diseases and inherited disorders," said Petra Furu, general manager of reproductive health at PerkinElmer. "This authorization is a major milestone for newborn screening in the United States. Labs across the country will be able to access technologies that detect SMA and SCID, and provide them the confidence that every test meets regulatory, manufacturing and accreditation requirements."

The EONIS Platform is a robust, flexible system that utilizes real-time PCR technology to screen for both SMA and SCID using a single dried blood spot sample, combining DNA extraction and multiplexing. When combined with PerkinElmer's JANUS® liquid handler, PerkinElmer's workflow allows for maximum automation and efficiency, and can be configured to a laboratory's individual requirements and throughput. Other components of the platform include the EONIS™ DNA Extraction kit and EONIS™ Analysis Software.

The EONIS Platform is already **CE-IVD marked** for use by certified laboratories in countries that accept the CE mark.

As the global leader in newborn screening, PerkinElmer offers solutions to help identify more than 50 congenital disorders. On average, these solutions help save the lives of 70 babies each day. To learn more about PerkinElmer's comprehensive range of newborn screening offerings and their impact globally, visit [this webpage](#).

## About PerkinElmer

PerkinElmer is a leading, global provider of end-to-end solutions that help scientists, researchers and clinicians better diagnose disease, discover new and more personalized drugs, monitor the safety and quality of our food, and drive environmental and applied analysis excellence. With an 85-year legacy of advancing science and a mission of innovating for a healthier world, our dedicated team of more than 16,000 collaborates closely with commercial, government, academic and healthcare customers to deliver reagents, assays, instruments, automation, informatics and strategic services that accelerate workflows, deliver actionable insights and support improved decision making. We are also deeply committed to good corporate citizenship through our dynamic ESG and sustainability programs. The Company reported revenues of approximately \$5 billion in 2021, serves customers in 190 countries, and is a component of the S&P 500 index. Additional information is available at [www.perkinelmer.com](http://www.perkinelmer.com). Follow PerkinElmer on [LinkedIn](#), [Twitter](#), [Facebook](#), [Instagram](#), and [YouTube](#).

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