

FOR IMMEDIATE RELEASE

Hygiena[®] Becomes First Manufacturer with ISO 16140-2 Validation for Multiplex RT-PCR Detection of *Salmonella* and *Cronobacter*

First-ever ISO 16140-2 validated multiplex PCR assay for simultaneous detection of Salmonella and Cronobacter

Camarillo, CA – May 20, 2025 – Hygiena[®], a global leader in One Health Diagnostics[®] and food safety solutions is setting a new industry standard with the launch of its groundbreaking foodproof[®] *Salmonella* plus *Cronobacter* Detection LyoKit[®]. This innovative workflow solution is the first and only ISO 16140-2 approved rapid, real-time PCR test that enables manufacturers to detect both *Salmonella* spp. and *Cronobacter* spp. in a single assay, delivering unparalleled efficiency and regulatory compliance.

Ensuring the safety of infant formulas and related ingredients is a top priority for manufacturers worldwide. Regulatory agencies such as the FDA, EFSA, FSANZ, and SAMR mandate stringent testing protocols to prevent contamination by *Salmonella* and *Cronobacter*, two pathogens that pose serious health risks to infants. Traditionally, food safety laboratories performed separate tests for each pathogen, which increased costs and delayed results. Hygiena's foodproof *Salmonella* plus *Cronobacter* Detection LyoKit eliminates this inefficiency by detecting both pathogens in a single test, streamlining workflows and accelerating time-to-results for infant formula producers, ingredient suppliers and environmental monitoring programs.

"At Hygiena, we are committed to delivering solutions that not only meet but exceed industry standards in food safety," said Steve Nason, CEO of Hygiena. "By introducing the foodproof *Salmonella* plus *Cronobacter* Detection LyoKit, we are providing manufacturers with a faster, more cost-effective and highly reliable testing method that ensures compliance and safeguards consumers. This is a significant step forward in our mission to create innovative diagnostics for a healthier world."

The foodproof *Salmonella* plus *Cronobacter* Detection LyoKit is validated according to the ISO 16140-2 standard by AFNOR Certification. This validation ensures high accuracy across a range of matrices, including powdered infant formula (both with and without probiotics), related production ingredients and environmental samples from manufacturing facilities.

Hygiena is offering the first-ever multiplex PCR method specifically designed to address the unique pathogenic challenges of the powdered infant formula industry. In response to evolving industry practices, this groundbreaking method has been validated for test portion sizes up to 375 grams, ensuring it meets the stringent needs of end-users while delivering robust and reliable results. The ISO 16140-2 performance metrics provide food safety teams with reliable, specific, sensitive, reproducible and regulatory-compliant pathogen detection results.



Speed is crucial in food safety testing and the foodproof *Salmonella* plus *Cronobacter* Detection LyoKit delivers results in just 19 hours. Unlike alternative methods that require 18–20 hours of incubation for a single pathogen target, Hygiena's test reduces the enrichment time to 16 hours while detecting both *Salmonella* and *Cronobacter* simultaneously. This accelerated process enables manufacturers to reduce holding times, cut costs and minimize the risk of product recalls.

Designed for ease of use, the foodproof *Salmonella* plus *Cronobacter* Detection LyoKit features a streamlined workflow that enhances stability with lyophilized reagents, reduces contamination risks and integrates seamlessly with existing laboratory systems such as the BAX[®] System Q7. The simplified process requires minimal training, making it accessible to a broad range of laboratory personnel.

The foodproof *Salmonella* plus *Cronobacter* Detection LyoKit joins Hygiena's comprehensive suite of ISO 16140-2 validated assays, including those for *Listeria* spp. and *L. monocytogenes*, ensuring robust and reliable pathogen detection across various food matrices. Food protection is a non-negotiable priority, and our extensive validated portfolio provides manufacturers with reliable solutions that ensure compliance while protecting consumer health.

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We create innovative diagnostics for a healthier world

About Hygiena

At Hygiena, our mission is to create innovative diagnostics for a healthier world. We develop, produce and provide best-in-class One Health Diagnostics[®] solutions from farm to fork to our global customer bases. As one of the few organizations in the world to uniquely focus on food safety throughout the value chain, we maintain the belief that the health of people is closely connected to the health of animals in our shared environment. Our molecular rapid tests and analysis tools for food and beverage safety, veterinary diagnostics and environmental monitoring help prevent illness, save lives and contribute to making the world a safer place. As the global leaders in rapid diagnostic tests, we provide solutions that are reliable, easy to use and accurate, backed by industry-leading customer service and support. With a sizeable global presence, Hygiena is headquartered in Camarillo, California with numerous offices and customer application centers in the Americas, Europe, Africa, Asia and Australia. We also partner with over 180 distributors in more than 100 countries worldwide. Learn more about us at www.hygiena.com.

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