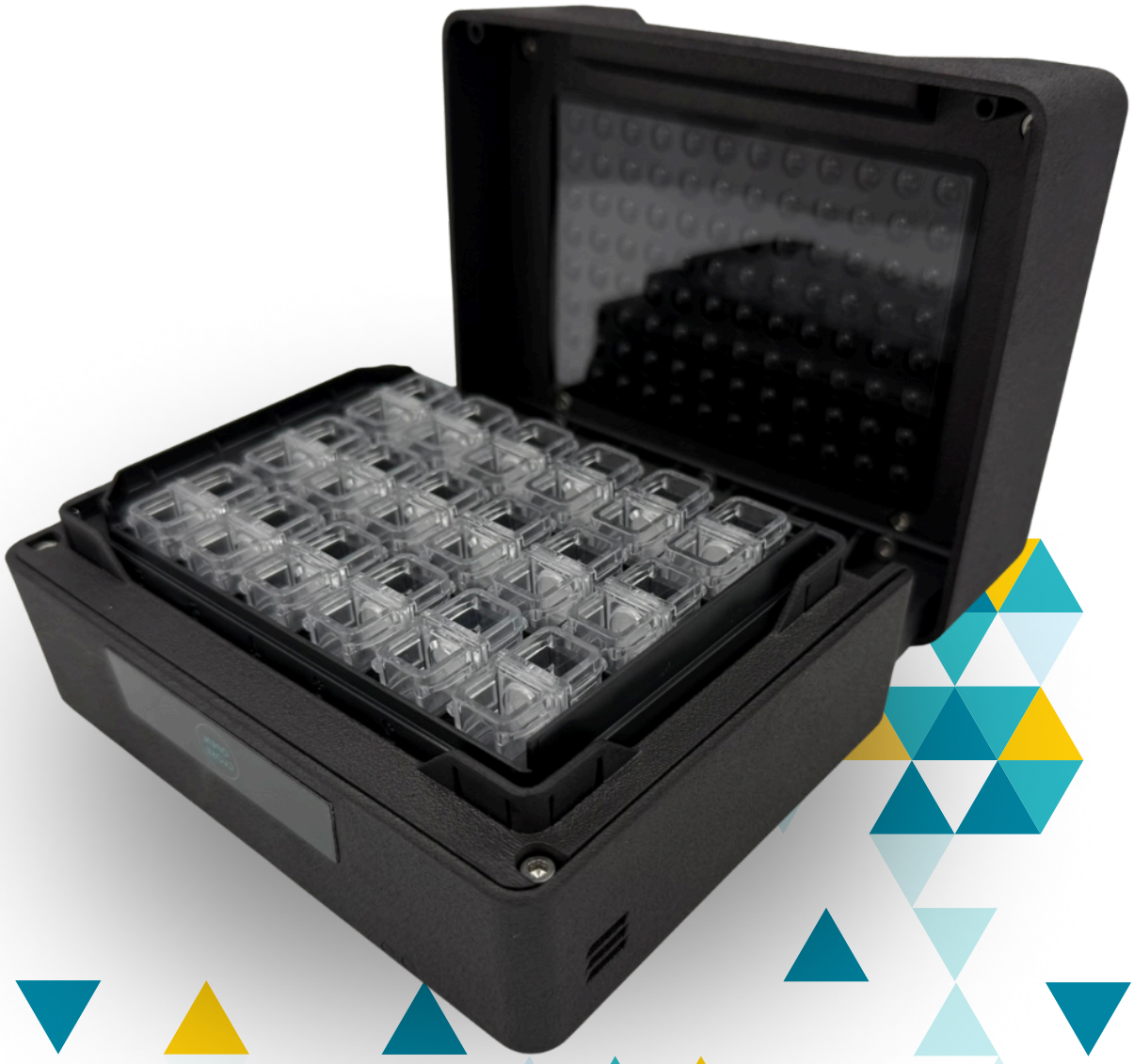
cerillo
illuminate possibility

Beyond the Bench

Portable Testing for Probiotic Quality and Compliance



Beyond the Bench

How Portable Testing Protects Probiotic Quality and Consumer Trust

In the last fifteen years, the probiotic industry has exploded. From grocery store shelves to clinical trials, probiotics are now a fixture of modern wellness and medicine. Fueled by consumer demand and scientific breakthroughs, the global probiotics market is growing fast—and diversifying across industries. According to the USDA Agricultural Research Service (ARS), the global probiotics market was valued at $58 billion in 2021 and is projected to surpass $110 billion by 2030, with some estimates as high as $220B (Grand View Research). This market growth is led by demand from food and beverage producers, supplement manufacturers, and disease-focused research.

Three major sectors are leading this transformation

Disease-Focused Research

Innovative studies are applying probiotics to areas like cancer immunotherapy and chronic disease treatment.

Food & Beverage

Probiotic yogurts, drinks, and functional foods are staples of modern health routines.

Pharmaceuticals & Supplements

Capsules and tablets for gut and immune health remain core delivery methods.

Yet with growth comes new challenges—and high stakes. Probiotics are live microorganisms. If manufacturing, packaging, storage, or distribution go wrong, the result can range from reduced product effectiveness to severe illness. Beyond safety risks, there are regulatory, legal, and reputational consequences for failing to meet standards or substantiate marketing claims.

Recent history shows how costly and dangerous manufacturing or quality control failures can be:

Ozona Organics Probiotics & GoHealthy Liquid Probiotics (Aug 2023)

Recalled due to microbial growth capable of causing illness. Lawsuits are being accepted related to severe infections after consumption.

MaryRuth's Liquid Probiotic for Infants (Aug 2023)

Recalled due to the presence of Pseudomonas aeruginosa, a dangerous bacterium for immunocompromised infants. Lawsuits are being accepted for injuries linked to this contamination.

Align Probiotic (Procter & Gamble, filed 2010, settled 2017)

Faced a class action lawsuit alleging false advertising about product effectiveness. Case was settled for $30 million.

ABC Dophilus Powder (Solgar Inc., 2014)

A premature infant died after exposure to a fungus-contaminated probiotic powder. A lawsuit filed by the infant's estate claimed the contamination caused sepsis and death.

The message is clear: safe, compliant, and validated manufacturing is not optional—it's mission-critical.

The Challenge of Real-World Testing

Why Portability Matters

Current probiotic research is constrained by the lack of accessible, real-time tools for monitoring growth kinetics especially in multi-strain consortia or under stress conditions that mimic real-world use. Traditional lab equipment is often bulky, fragile, expensive, and not optimized for co-culture or high-throughput screening.

When testing only happens in centralized labs, companies risk delays, incomplete data, and missed opportunities to identify problems early. The solution lies in moving testing capabilities into the same spaces where probiotics are actually made, packaged, and stored. In today's regulatory climate, it has never been more critical for companies to ensure these spaces maintain rigorous quality control and adhere to bold 21 CFR Part 11 guidelines to safeguard product integrity and compliance.

Kurt Fenster explains in The Production and Delivery of Probiotics: A Review of a Practical Approach:

> *As ever-more probiotics are being consumed by the general population... the standards and rules for maintaining QC labs and testing have advanced. Compliance with regulatory guidance and applicable standards have improved the control and outcome of production and QC processes, augmenting the ability of production facilities to produce and QC to release a more consistent end-product.*
>
> *(Fenster, 2019, p. 6)*

Examples of Regulatory Guidelines for Quality Control

Regulation	Description
21 CFR 117	Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls For Human Food
21 CFR 111	Current Good Manufacturing Practice In Manufacturing, Packaging, Labeling, Or Holding Operations For Dietary Supplements
ICH Q7	Good Manufacturing Practice Guide For Active Pharmaceutical Ingredients

Why Portable, Real-Time Testing Changes the Game

For companies developing probiotic-enhanced foods, supplements, or even therapies, manufacturing-based data delivers:

1 Real-Time Quality Monitoring

- Use absorbance (e.g., OD600) to monitor fermentation kinetics
- Rapidly detect contamination or suboptimal growth
- Make adjustments early to avoid costly yield losses

2 Digital Data Capture & Integrity

- Record and store electronic data that complies with 21 CFR Part 11
  - Secure audit trails
  - Role-based access
  - Timestamped records
  - Watermarked exports
  - User authentication

3 Reduced Regulatory Risk

- Complying with 21 CFR Part 11 reduces exposure to FDA inspection issues or warning letters
- Complying with 21 CFR Part 11 reduces exposure to FDA inspection issues or warning letters

4 Operational Efficiency

- Streamline testing during fermentation, drying, packaging, and storage
- Use portable readers directly in manufacturing spaces to minimize sample handling and lab delays

Testing in the production environment enables faster iteration, more confident decision-making, and substantial savings across the development pipeline. Compact, real-time tools allow teams to generate relevant, high-quality data exactly where it matters—on the production floor, not weeks later in a remote lab.

Wireless connectivity adds another layer of complexity, as many production sites lack stable internet or cloud access. This makes remote monitoring, real-time collaboration, and automatic data syncing difficult and creates friction across the R&D and commercialization process.

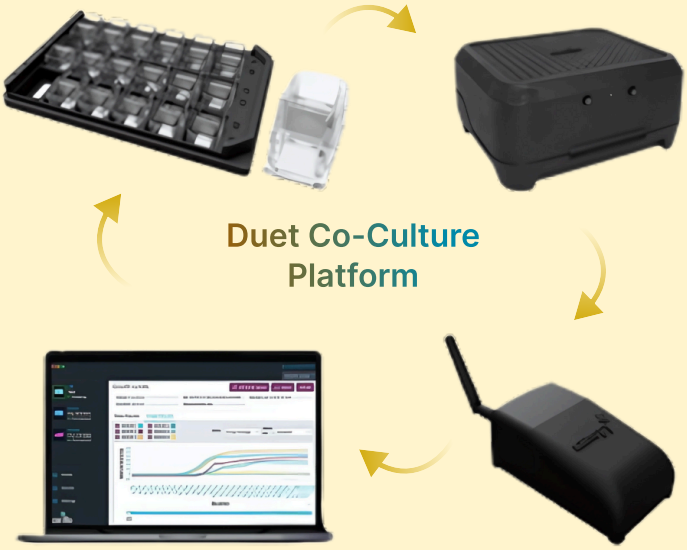
The ideal solution must combine rugged portability, environmental versatility, and wireless functionality with low overhead & simple deployment. This enables a shift from centralized testing to real-time, point-of-process analysis—accelerating discovery, ensuring quality, and supporting modern manufacturing workflows. The probiotic industry is evolving—so why is testing still stuck in the lab? It's time to solve the real-world challenges of production, stability, and compliance.

Cerillo Research Platform vs. Traditional Microplate Reader

Features	Cerillo's Microplate Reader	Traditional Microplate Reader
Portable	✅ Yes	❌ No
Works in volatile environments	✅ Yes (heated, shaking, anaerobic)	❌ No
Wireless + remote access	✅ Yes (Labrador + Canopy)	❌ No native wireless
Setup simplicity	✅ Plug-and-play	❌ Requires software setup
Operates in real time in situations	✅ Yes	❌ No
Cost and footprint	✅ Low	❌ High

Cerillo's Duet Co-Culture Platform

It's not just a tool. It's a rethink of how we study life at the microbial level.



Your Complete Solution to:

- ✅ Accelerate discovery
- ✅ Reduce risk
- ✅ Save time
- ✅ Drive decisions
- ✅ Enhance reliability
- ✅ Increase mobility

850+ Global Users. One Proven Solution.

Cerillo's Research Platform for Probiotic Discovery

With more than 850 global users, Cerillo has proven that real-world probiotic testing is not just possible—it's already happening. Compact, portable, and built for manufacturing constraints, Cerillo's platform allows companies to execute high-quality experiments exactly where probiotics are made, stored, and consumed. It is designed specifically for microbial discovery within dynamic manufacturing settings. Built with manufacturing constraints in mind—space, power, wireless connectivity, and usability—its tools allow researchers to run high-quality experiments in environments that better reflect how probiotics are manufactured, stored, and consumed.

Cerillo's Microplate Reader - Lab-Grade Insights.

Anywhere You Need Them.

Cerillo's reader is built to accelerate probiotic discovery, reduce production risk, and streamline decision-making—right where it counts: on the production floor, in the fermenter, at the drying stage, during post-packaging QA, or even throughout shipping and storage. Compact yet powerful, it brings kinetic and endpoint measurement capabilities into the real-world conditions where probiotic viability can make or break a batch.

- **Accelerate discovery** with rapid on-site testing
- **Reduce risk** by identifying viability issues early
- **Save time** by eliminating sample transport delays
- **Increase mobility** with a system that fits in the palm of your hand
- **Enhance reliability** with lab-quality performance in tough conditions
- **Drive decisions** with real-time data

Features	Benefit
Compact, hand-held design (10× smaller than benchtop readers)	Enables on-the-spot testing and fits seamlessly into GMP workflows
Flexible Plate Compatibility: Compatible with 6-, 12-, and 96-well plates	Allows flexible, parallel testing across various product formats
Functions in anaerobic, heated, and shaking environments	Tracks real-time viability during key processing stages
Multi-wavelength support (405–740 nm)	Enables ELISA, fluorescence, and viability assays across R&D and production
Standalone Operation: Standard software with microSD, manual control, and USB	Enables ELISA, fluorescence, and viability assays across R&D and production

Duet The Industry's First Standardized Co-Culture System

Understand Microbial Behavior Before It's too Late.

Duet is the first standardized co-culture consumable designed for researchers and manufacturers who need to go beyond single-strain testing. It lets you model real-world microbial dynamics (competitive inhibition, cross-feeding, and metabolite exchange) in the same types of environments where your products are made to work.

- **Accelerate discovery** by identifying synergistic strain combinations
- **Reduce risk** by exposing problem interactions early
- **Drive decisions** with functional, reproducible data
- **Enhance reliability** through simulations of gut-like or production-level stress
- **Save time** by replacing trial-and-error with focused design
- **Increase flexibility** by testing outside centralized facilities

Features	Benefit
Real-time observation of strain–strain interactions	Reveals synergy or inhibition in multi-strain probiotic blends
Real-Time Growth Tracking	Informs formulation and packaging decisions based on functional data
Gut-like stress simulation	Informs formulation and packaging decisions based on functional data
Monitors behavior during co-culture and metabolite shifts	Informs formulation and packaging decisions based on functional data

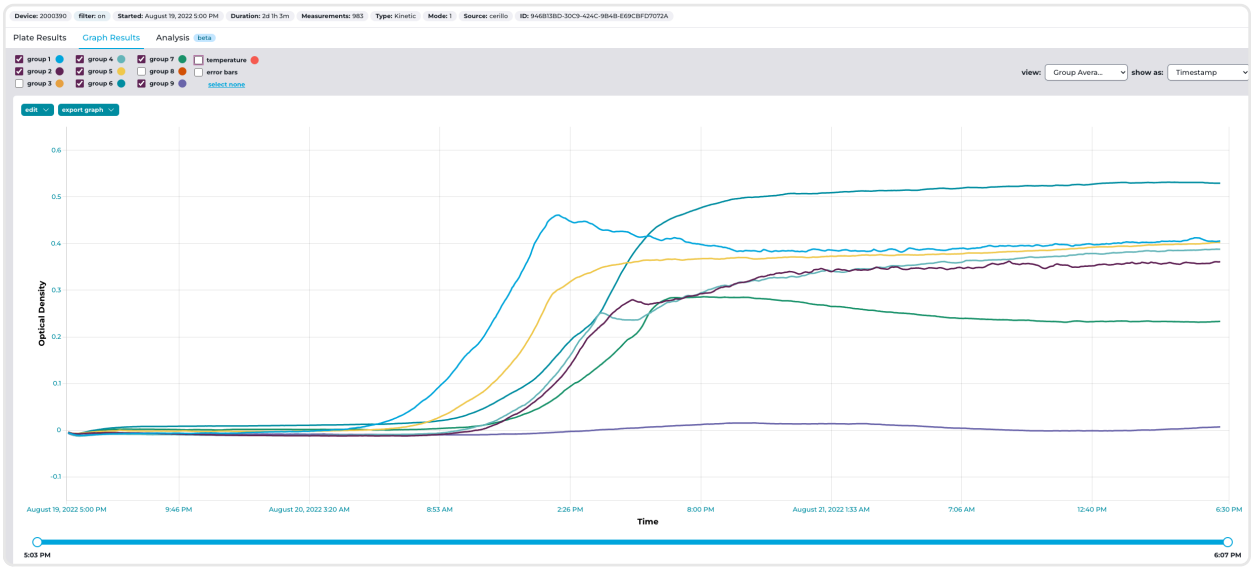
Labrador + Canopy

Seamless Data. Smarter Decisions. Remote Control.

Labrador is the software backbone of the Cerillo's Duet Co-Culture Platform—designed to capture, store, and analyze critical data from wherever testing takes place. The optional Canopy integration solves the wireless connectivity challenge.

- **Save time** by automating data collection and syncing
- **Reduce risk** with traceable records across locations
- **Drive decisions** with real-time experiment visibility
- **Enhance reliability** with standardized control across experiments
- **Increase mobility** by enabling remote monitoring and control
- **Increase mobility** by enabling remote monitoring and control

Features	Benefit
Intuitive Software for Data Visualization	Streamlined experiment setup and presentation-ready growth curve graphs,
Premium version with Canopy for wireless/ cloud monitoring	Enables remote experiment control and real-time collaboration



Closing the Loop on Quality

Duet's Role in Probiotic Success

Duet Co-Culture System

Use Case Benefits for Probiotics:
Supporting Every Stage from Manufacturing to Storage

1

Manufacturing
Monitor fermentation kinetics (OD600) in real time to detect and correct performance issues early.

2

Drying
Rapidly assess post-drying cell viability in freeze- or spray-dried products.

3

Packaging
Compare probiotic stability across different packaging types and storage conditions -without the lab.

4

Shipping
Validate product integrity at warehouses, loading docks, or delivery checkpoints.

5

Storage
Identify subtle changes in microbial activity caused by prolonged storage or fluctuating warehouse conditions, enabling proactive shelf-life adjustments or distribution rerouting.

Unlocking the Future of Probiotic Innovation

As probiotic applications expand across gut health, disease treatment, and functional foods, companies must evolve beyond static R&D models. Lab-only protocols are no longer enough. To compete—and to deliver on growing consumer and clinical expectations—organizations need research solutions that operate in the real world where their products are used.

Cerillo's proven, portable platform empowers researchers to accelerate discovery, validate claims earlier, reduce product risk, and operate with flexibility across the probiotic landscape. The Duet Co-Culture System transforms the validated science of microplate-based viability screening into a platform that thrives where traditional tools cannot: in real-world manufacturing environments. By enabling on-site testing that complies with 21 CFR Part 11 data integrity requirements, Cerillo helps companies maintain rigorous quality control. This approach protects brands from costly class action lawsuits, prevents product recalls, and safeguards both consumer trust and long-term market success. **It's time to bring your research to the manufacturing environment—and your innovations to life.**

Visit www.cerillo.bio or contact us at info@cerillo.bio to learn more.