

**FULLY  
AUTOMATED**  
COMPENDIAL TESTING

**FULLY  
SUPPORTED**  
EVERY STEP OF THE WAY

**ENSURING RAPID, RELIABLE,  
SECURE, AUTOMATED QUALITY  
CONTROL (QC) THROUGHOUT YOUR  
QC MICRO PROCESS**



# TRADITIONAL QC METHODS PUT YOUR BUSINESS AT RISK

## MANUAL TESTING CAN BE COSTLY FOR YOUR BRAND

Manufacturing facilities face ever-increasing demands for greater production capacity. These demands drive up test volume in the microbiology QC lab, where reliable results and regulatory compliant process and documentation are expected, all with limited resources.

As the industry moves forward with increased automation and smart manufacturing initiatives, relying on current manual testing methods could leave your facility behind. Compendial testing is labor-intensive, produces slow results that are prone to human error, and is vulnerable to tampering and poor compliance:

- During incubation, plates can be misplaced, mislabeled, or discarded before they've been fully analyzed
- During enumeration, miscounting can result in interim colony counts that are higher than final totals
- Data entry presents opportunities for transcription errors
- The result is operational and labor inefficiency, increased risk of errors, and lost time, all of which lead to regulatory risks and can be costly to your brand and your bottom line

Growth Direct® QC automation increases efficiency, ensures data integrity, streamlines QC, and reduces organizational risk.

Put it to work for you.

Growth Direct® is the only fully automated, non-destructive growth-based system for multiple QC test applications: environmental monitoring, water, and bioburden, providing you with:

- Faster results
- Eliminates human error due to misplaced or mislabeled plates, miscounts, and transcription mistakes
- Ensures data integrity and sample security
- Virtually eliminates hands-on labor
- Designed to be compliant with 21 CFR Part 11 requirements





## IMPLEMENTATION AND VALIDATION

**BRINGING YOU UP TO PRODUCTION AS QUICKLY AS POSSIBLE**

### Installation

On-site unpacking and installation of Growth Direct® to ensure quick IOQ readiness.

### Training

Comprehensive training to help your team quickly and thoroughly understand key concepts and uses of Growth Direct®.

### Validation support

We provide a complete array of documents and services to support every step of your validation process, including:

- Validation project management
- Installation and operational qualification
- Performance qualification
- Time to result analysis
- Method suitability

### Software integration

Seamless connectivity and integration with your LIMS platform.



## PREPARING FOR IMPLEMENTATION

### OUR SUPPORT SERVICES BEGIN EVEN BEFORE THE SALE

#### Pre-purchase activities

On-site visit to understand your environmental monitoring and bioburden testing needs, processes, lab workflow, and impact to manufacturing.

#### Process analysis

Discussion of your current processes and development of strategies to simplify and accelerate implementation of Growth Direct®.

#### QA documentation support

Review of your documentation requirements and processes to help ensure a quick and seamless validation process.

#### ROI support

Assistance in developing a compelling business case to support your purchase.

#### Implementation planning workshop

A moderated discussion among key stakeholders to help align the validation and implementation strategy with your business process.

#### Technical support

Assistance in implementing required technical services, including:

- 21 CFR Part 11 compliance assessment
- Data integrity assessment
- IT connectivity between Growth Direct® and your host network
- Optional integration with your laboratory information management system (LIMS) to enable bi-directional interface with the system software
- Remote monitoring capability by the Rapid Micro Biosystems service team to evaluate system performance and quickly resolve issues

# ONGOING SUPPORT

## COMPREHENSIVE MAINTENANCE PACKAGES TO ENSURE SYSTEM AVAILABILITY

### EXTENDED AVAILABILITY

Rapid Micro Biosystems offers customer support 7 days a week during normal business hours in the U.S. (7:00 AM - 6:00 PM EST), Europe (7:00 AM - 6:00 PM EU CET), and Asia Pacific Regions (8:00 AM - 6:00 PM SGT JST KST AEST).

### USER SUPPORT

Frontline support for questions on the proper use, quality, and performance of Growth Direct® products.

### PREVENTIVE MAINTENANCE ACTIVITIES

Our support agreement includes two on-site visits per year for preventive maintenance, regular component inspections, and system performance monitoring.

### SYSTEM SUPPORT

Field service engineers are on call and available to handle system service and repairs. Our Premier Service package includes on-site response time within 24 hours.





# EMPOWER YOUR LAB WITH THE CONFIDENCE OF AUTOMATION

Growth Direct® is the only fully automated, non-destructive growth-based system for multiple QC test applications:  
environmental monitoring,  
water, and bioburden.

Growth Direct® delivers fast, accurate results, ensures data integrity compliance, increases lab efficiencies, decreases hands-on labor, and virtually eliminates human error.

See how the Growth Direct® System can help you automate your environmental monitoring, water, and bioburden testing improving your facility control.



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