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

FULLY AUTOMATED
COMPENDIAL TESTING

FULLY SUPPORTED
EVERY STEP OF THE WAY

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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 is the first and only growth-based system to automate compendial testing, providing you with:

- 50% faster results
- Eliminates human errors due to misplaced or mislabeled plates, miscounts, and transcription mistakes
- Ensures data integrity and sample security
- Virtually eliminates hands-on labor
- Compliant with the requirements of 21 CFR Part 11

Growth Direct QC automation increases efficiency, ensures data integrity, streamlines QC, and reduces organizational risk. **Put it to work for you.**
**IMPLEMENTATION AND VALIDATION**

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

**Installation**
On-site unpacking and installation of Growth Direct to ensure quick IQ/OQ 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) and Europe (7:00 AM - 6:00 PM EU CET).

**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.
Growth Direct is the first and only growth-based system that fully automates compendial testing for three important QC applications: Environmental Monitoring, Bioburden, and Water Testing.

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, bioburden, and water testing and improve your facility control.