FULLY AUTOMATED
COMPENDIAL TESTING

FULLY SUPPORTED
EVERY STEP OF THE WAY

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

Rapidmicro biosystems

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® is the only fully automated, non-destructive growth-based system for multiple QC test applications: environmental monitoring, water, and bioburden. Benefits of automating your process:

- 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

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 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

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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.

GrowthDirect
Instrumental to your success

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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PURPOSELY DESIGNED FOR REGULATED MICROBIOLOGY DEMANDS

Designed for maximum throughput with minimal load times

- Continuously process up to 660 samples at two different temperatures

- Two input queues with removable carousels load up to 120 EM, bioburden, or water cassettes

- Automatically loads up to 60 cassettes at a time in under 20 minutes

Thoughtful features that make the QC process more efficient

- In-specification cassettes automatically moved to biohazard waste bin

- Central output queue holds 10 cassettes flagged for further investigation

Robust regulatory compliance data at your fingertips

- Real-time reads per cassette are displayed and retained with full audit trails

- Standard reports tailored to your QC needs

- Supports 21 CFR Part 11 compliance
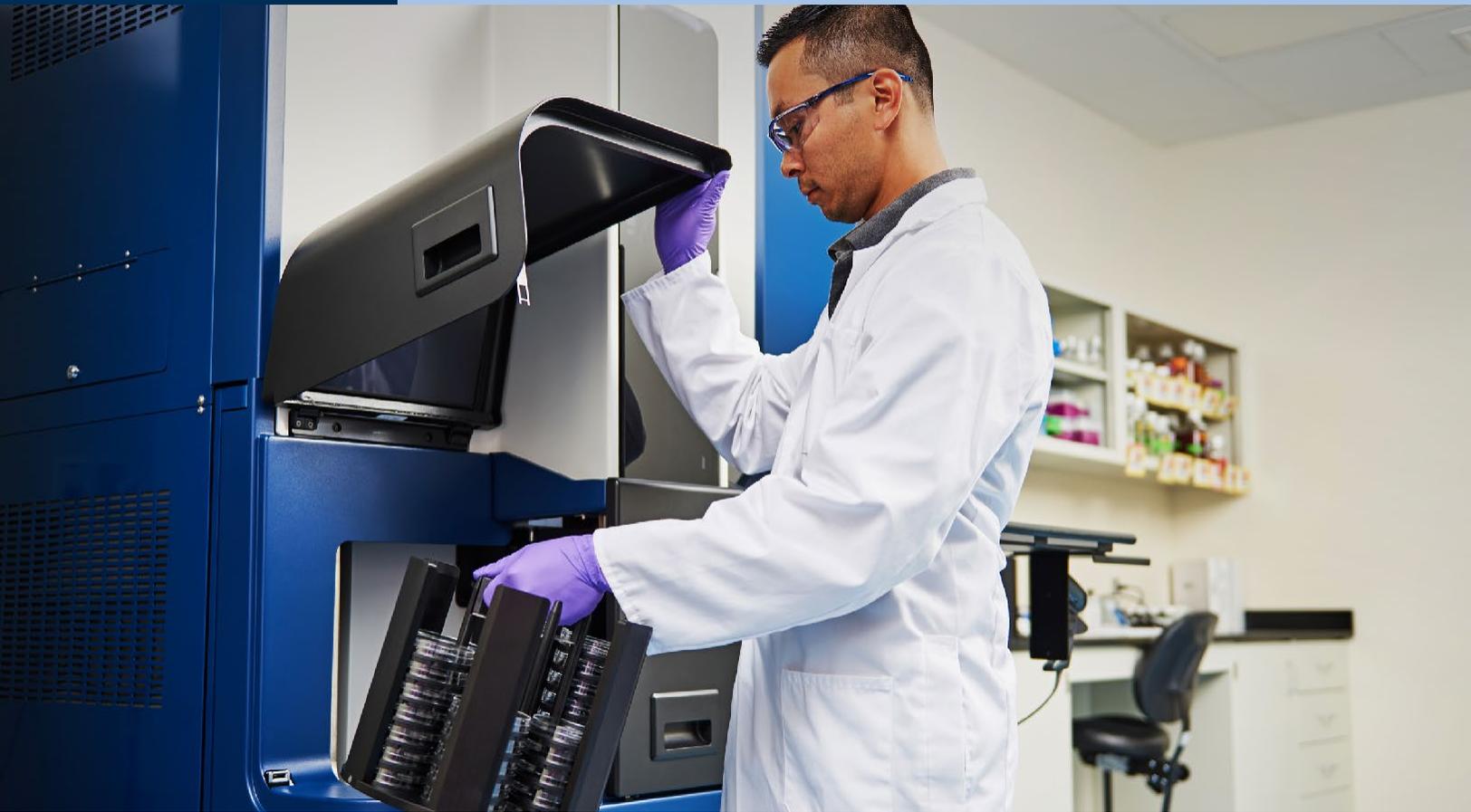
- LIMS-capable data and assay management

INSTRUMENT INTERNAL VIEW

Each independently controlled incubator can hold up to 330 environmental monitoring, water, or bioburden cassettes

USER INTERFACE (UI)

Touchscreen UI displays system health, diagnostics, user commenting, read-only cassette data, and report approval

THE GROWTH DIRECT® SYSTEM WAS SPECIFICALLY DESIGNED TO HANDLE THE UNIQUE REQUIREMENTS OF QUALITY CONTROL MICROBIOLOGY TESTING NEEDS FOR PRODUCT MANUFACTURING

- Growth Direct® can be installed in a controlled manufacturing or lab environment

- System reads cassettes every 4 hours and immediately reports results

- Email notifications for out-of-specification (OOS) results, allowing users to make decisions and take remediation steps right away

- High-capacity dual incubators allow for large test volumes at single temperature or automated serial temperature assays

- Advanced technology supports concurrent processing of multiple test protocols and assays simultaneously, including:

  - Incubation time and temperature

  - Automated cassette transfers between incubators for sample incubation

- System can be operated as a stand-alone instrument or interfaced with your laboratory information management system (LIMS)

AUTOMATE YOUR BIOBURDEN, ENVIRONMENTAL MONITORING, AND WATER TESTING

STREAMLINED PROCESSES. INCREASED PRODUCTIVITY. FEWER ERRORS.

Achieve greater reliability, efficiency, and predictability than ever before with Growth Direct®.

CUSTOMARY MEDIA, EXTRAORDINARY VALUE

The combination of Growth Direct® and its cassettes provides final sample results up to twice as fast as a traditional compendial test, revolutionizing the testing and analysis of your quality control (QC) samples.

Our cassettes use standard pharmacopeial media such as R2A for water testing, Sabouraud Dextrose Agar (SDA) and Tryptic Soy Agar (TSA) for bioburden testing, and TSA LP80 (lecithin and polysorbate 80) for environmental monitoring (EM). The media are provided in a traditional compendial equivalent format, simplifying validation.

TIME-SAVING VALIDATION

Growth Direct® is a growth-based test that uses no reagents. Flagged positive samples can either remain in the Growth Direct® or can be removed for incubation in the same cassette. These can then be sent to a microbial identification system for further analysis, resulting in critical time savings during investigations.

DESIGNED FOR SUCCESS

Our cassettes are designed to enable the automated system to detect positive results faster and more accurately than by standard methods. The cassette format has been optimized and tested for both ease of operator use and system throughput.
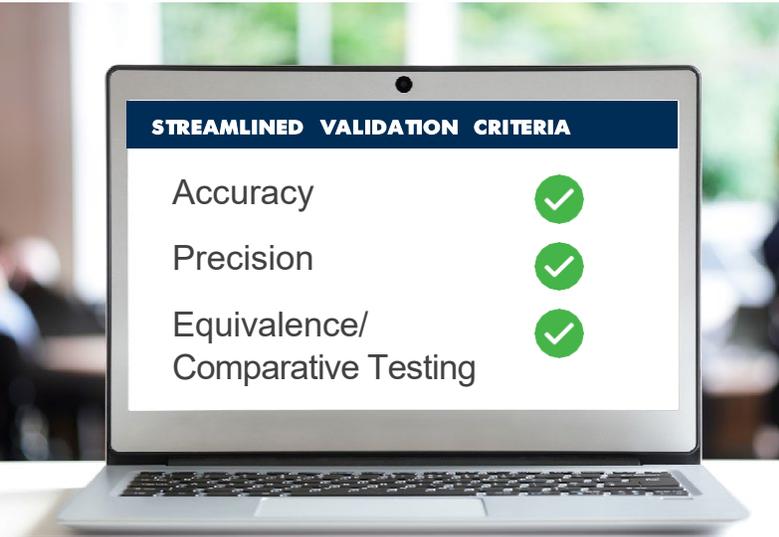
DURABLE, HIGH-QUALITY CONSUMABLES

Our automated manufacturing line produces high volumes of media-filled cassettes in a controlled clean room environment and appropriately irradiated to ensure high quality and long shelf life. Consumables are shipped via our global supply chain for prompt material support.

ORDERING INFORMATION

CONSUMABLES: GROWTH DIRECT® FOR WATER AND BIOBURDEN

Item No.	Description
BR2A-048	Bioburden Cassettes, R2A, 48 cassettes/case
BSDA-048	Bioburden Cassettes, SDA, 48 cassettes/case
BTSA-048	Bioburden Cassettes, TSA, 48 cassettes/case
B150-048	Bioburden Filtration Funnels, 150mL, 48 funnels/case
B250-048	Bioburden Filtration Funnels, 250mL, 48 funnels/case
BBVL-048	Bioburden vision lids, 48 lids/case

Choices include R2A agar for water testing, Sabouraud Dextrose Agar (SDA) for yeasts and molds, and Tryptic Soy Agar (TSA) for general product testing.

CONSUMABLES: GROWTH DIRECT® FOR EM

Item No.	Description
ET80-100	Environmental Monitoring Cassettes, TSA LP80, 100 cassettes/case
ET80HT-100	Environmental Monitoring Cassettes, TSA LP80HT, 100 cassettes/case
EMVL-100	Environmental Monitoring Vision Lids, 100 lids/case

Our EM cassettes leverage industry-standard media, including TSA with LP80 and TSA with LP80HT (lecithin, polysorbate 80, histidine and thiosulphate).

WE HAVE YOUR VALIDATION COVERED

STREAMLINED VALIDATION CRITERIA

Accuracy ✓

Precision ✓

Equivalence/ ✓
Comparative Testing

AN APPROVED AND PROVEN VALIDATION FORMAT

Growth Direct® not only enables faster and more accurate environmental and bioburden microbial testing, it is also straightforward to validate. The system can be validated using an automated compendial approach as specified in USP Chapter <1223>, PDA Technical Report 33 (TR33), and with project management services, validation can be completed in less than six months. This automated compendial approach only requires the assurance of accuracy, precision, and equivalence as compared to the reference standard. It has been successfully reviewed with the FDA and EMA, and has been used by multiple US and EU companies.

The Rapid Micro Biosystem approach validates the automated enumeration system and the electronic transfer of data (including through your laboratory information management system [LIMS]). This approach has supported numerous pharmaceutical sites in the validation of Growth Direct® for use in environmental and bioburden testing.

OUR TEAM CAN ASSIST YOU THROUGHOUT THE PROCESS

Resources at pharmaceutical companies are in high demand. Often, competing priorities don't leave much time to focus on validation projects.
But even though the process is fairly straightforward, successful validation still requires planning, resources, and management.

Our skilled validation team can help, by providing a complete suite of validation documents, services, and project management to ensure timely qualification of your Growth Direct® System, covering all the steps in the validation process:

- Installation and operational qualification (IOQ)
- 21 CFR Part 11 assessment
- Performance qualification
- Time to result analysis
- Method suitability

The Rapid Micro Biosystem all-inclusive, comprehensive validation package includes a dedicated project manager who oversees and conducts your validation, progressing you through each of the commissioning and qualification steps.

ALL INCLUSIVE SERVICE PACKAGE FEATURES

Dedicated project management: A Rapid Micro Biosystems validation specialist oversees the entire validation process from IOQ through routine use.

Committed resources execute protocols: A trained validation specialist will execute the validation protocols and drive the project forward.

Complete document package: Includes user requirements, use instructions, installation and operation qualification, performance qualification, time to results analysis, and method suitability.

Optimized validation timeline: On average, companies will complete validation in six months. With prioritized review by internal sign-off groups, companies can validate in as few as four months.

	MONTH 1	MONTH 2	MONTH 3	MONTH 4	MONTH 5	MONTH 6
1. Pre-Installation						
2. System Installation						
3. System IT/LIMS Setup						
4. Installation and Operational Qualification						
5. Performance Qualification						
6. Method Qualification						LIVE

■ RMB ■ Customer

SEAMLESS INTEGRATION WITH YOUR LIMS

Bi-directional LIMS integration: Bi-directional interface with the system software means results can be retrieved from the operator's desk terminal, or sample test lists can be downloaded remotely to the system for analysis. Data from Growth Direct® can be transferred to any number of different LIMS and other networked programs, such as EM trending databases. Growth Direct® creates a standard export file in .xml or .csv format, which can be parsed by networked programs to pull relevant data.

Quicker access to information: Test results are available to LIMS users as soon as the assay completes, leading to improved decision-making.

Review by exception: Reduce the amount of data review by automating the approval of passing results.

SUPPORTING YOUR BUSINESS NEEDS FOR THE LONG TERM

OUR COMPLETE SERVICE AND MAINTENANCE PACKAGE WILL HELP YOU MAXIMIZE THE PERFORMANCE OF YOUR GROWTH DIRECT® SYSTEM

Rapid detection, improved efficiency, and reduced investigations are critical to your business's ongoing success. With Rapid Micro Biosystems' Premier Services, you can be confident that your Growth Direct® System is fully supported with rapid response and maximized uptime.

Growth Direct® comes with an included one-year warranty. At Rapid Micro Biosystems, we are dedicated to ensuring that Growth Direct® helps your production facility achieve faster QC microbiology results with greater reliability, efficiency, and predictability. We offer a full service and maintenance package to support both the equipment and software, commencing upon warranty expiration.

Our Growth Direct® field service engineers (FSE) are fully trained and work in accordance with current good manufacturing practice (cGMP) standards. Our Premier Service package features next day on site response by an FSE in the event of a system issue.

Also included with your support agreement is twice-a-year preventive maintenance. Conducted by your Rapid Micro Biosystems FSE, this comprehensive maintenance includes:

- Inspection of electromechanical components
- Verification of sensor calibrations
- Replacement of required parts, if needed or scheduled
- Post-service readiness testing

In addition, Premier Service comes with basic system training and refresher training for all operators.

IMPROVING YOUR FACILITY'S PRODUCTIVITY WITH ADVANCED REMOTE MONITORING

The Remote Monitoring System (RMS) for Growth Direct® uses technologically advanced tools to ensure optimal system performance.

Our support team uses RMS to analyze system performance data and recognize trends to predict and prevent errors before they occur. We can then schedule preventive maintenance visits to avoid interruption of routine testing and maximize system uptime.

An innovative and secure web-based application, RMS also enables:

- Remote staff training on how to use the Growth Direct® interface
- A view of the system's operational status
- Access to individual action reports for each system
- Remote desktop connection for Rapid Micro Biosystems engineers or your own staff

SELECT THE RIGHT LEVEL OF SERVICE TO HELP OPTIMIZE YOUR LABS EFFICIENCY

Empower your lab to be more efficient than ever, with the right service package to serve your 24/7 operational demands.

RAPID MICRO BIOSYSTEMS SUPPORT AGREEMENTS	Service Level	
	Basic	**Premier**
Service Interventions		
Remote system monitoring	●	●
Response time, phone (during work hours)	●	●
Response time, on-site (during work hours)	72 hours	**24 hours**
Service repair visits (includes travel cost, labor, and repair parts[1])	2	**Included**
Application support	Available[2]	**10 days**
Preventive Maintenance Services		
Weekly review of system logs[3]	Available[2,3]	●
Two on-site preventive maintenance visits per year	●	●
- Inspect/align mechanical parts	●	●
- Inspect all pneumatic lines and cabling	●	●
- Check all belts and sensors	●	●
- CRU temperature testing	●	●
- Incubator temperature calibration	●	●
- Replace all system air filters	●	●
- Proactively address any wear points	●	●
- Mandatory software/hardware updates	●	●
Training – basic system training and refresher training for operators	Available[2]	●

[1]Does not include consumables, carousels, barcode labels, or damaged parts due to misuse
[2]Please call for a quote on this service
[3]Requires Remote Monitoring System of level 4 or higher
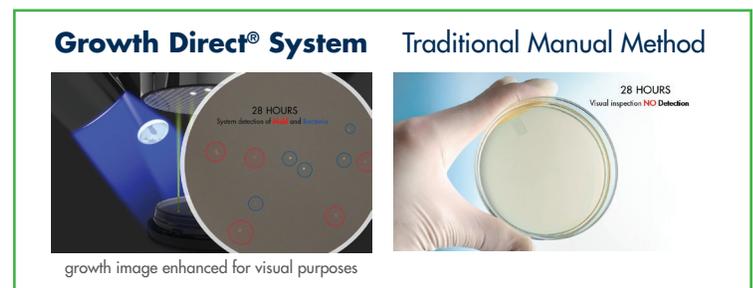
Mold Detection in Real Time

RMBNucleus™
Mold Alarm

- **Automated alerts** signaling the presence of mold at incubation
- **Detection** of molds that commonly cause microbial contamination
- **Rapid detection** in as little as 1 day
- **Enhanced data integrity**
- **Easy implementation** as part of your Growth Direct® System software

Proven Effective With:

Alternaria	*sp.*
Aspergillus	*fumigatus* *flavus* *brasiliensis* *versicolor*
Cladosporium	*cladosporioides* *herbarum*
Curvularia	*lunata* *pallescens* *verruculosa* *hominis* *pseudobrachyspora*
Fusarium	*keratoplasticum*
Penicillium	*chrysogenum* *notatum* *rubens*

*Based on initial feasibility performance data from internal 2022 Rapid Micro Biosystems study of 16 mold species incubated and tested in the Growth Direct® System EM cassettes.

Quick to spread and difficult to detect, molds can compromise a facility in the time it takes to confirm their presence. **RMBNucleus™ Mold Alarm** allows investigations to begin in as little as one day with automated alerts triggered by detection of molds during the early stages of incubation. Mold Alarm only requires an update of Growth Direct® System software, leaving your existing action alert limit values and cassette handling preferences intact—while adding a new, real-time course of action when mold is present.

Growth Direct® System   Traditional Manual Method

growth image enhanced for visual purposes

Real-time Mold Detection Matters

Slow detection and confirmation of mold recoveries continues to be a critical and current challenge within environmental monitoring (EM). The time to detect can allow mold spores to spread and cause major contamination compromising the manufacturing facilities and putting products and patients at risk. **RMBNucleus™ Mold Alarm** signals at the first sign of mold detection. This results in qualitative-actionable data communicated by automated emails and on-screen alerts, providing early intervention and remediation to improve regulatory compliance and reduce safety risks.

Data Integrity and Accuracy

Combining automated mold detection with seamless LIMs integration and a full audit trail, Mold Alarm reduces sources of human error while freeing staff from manual data entry. In a study utilizing a panel of 16 commonly recovered EM molds, Mold Alarm detected all molds present.

Contact Rapid Micro Biosystems at **support@rapidmicrobio.com** or call us at **978-349-3200**.