# A Modern View of QC Automation

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#### **SUMMARY**

With the launch of RMBNucleus™ software for the Growth Direct® System, Rapid Micro Biosystems offers customers the capability to coordinate hundreds of users and thousands of samples in real time without direct physical access. Other key features include Windows 10 and SQL Server 2019 architecture, full Microsoft support, and the latest security patches to optimize performance.



### INTRODUCTION

As pharmaceutical manufacturers unite advanced automation and real-time data analytics in pursuit of their Pharma 4.0™ goals, new standards of connectivity are emerging. We've witnessed this trend from the front lines at Rapid Micro Biosystems, helping customers to bridge laboratory and manufacturing operations after implementing the Growth Direct® System – often across multiple sites, and across multiple countries. Many users opt to have their Growth Direct® instruments interface with a laboratory information management system (LIMS), which then ladders up to the organization's manufacturing execution systems (MES); others simply opt to use their existing MES as a LIMS to reduce integration complexity. But in each case, new approaches bring new challenges.

In sharp contrast to the traditional image of microbiologists toiling over test samples at a lab bench, our emerging view of modern quality control (QC) is a network of Growth Direct® System instruments that swiftly test samples around-the-clock while sharing the results with users who can leverage their expertise without burdensome manual procedures. For maximum efficiency, however, a variety of issues must be addressed:

- System security and performance are now even more critical, with increased connectivity offering potential for enterprise-wide disruptions and compliance issues
- Reporting infrastructures don't always make it easy to support individual user needs, or to extract data for big-picture site evaluation
- User management can become cumbersome, with repetitious work needed to maintain roles, status, and access across each instrument
- Order management can be slow and error-prone due to file sharing from bridge computer to LIMS
- Evaluating system status often requires on-site physical access to individual automated systems

That's why Rapid Micro Biosystems is taking the Growth Direct® System to a higher level of integration by offering a <u>new software interface</u> – one with more flexibility than ever before, allowing our customers to coordinate literally hundreds of users and thousands of samples in real time.



### INTRODUCING RMBNucleus™

Summer 2022 marks the launch of a major software upgrade for the Growth Direct® System, with improved Windows 10 and SQL Server 2019 architecture, full Microsoft support, and the latest security patches to optimize performance. It's called RMBNucleus™ and includes new features such as:

- Browser-based portal for multi-system administration
- Flexible, web-based LIMS data transfer option
- Upgraded reporting and auditing for 21 CFR 11 compliance
- Streamlined recovery, remote monitoring, and user operation

Whether your lab has a single Growth Direct® System or multiple units, RMBNucleus™ offers at-a-glance transparency without the need for direct physical access. Remote administrators can add users for multiple instruments in a single step, see which samples are in each unit for optimal cassette handling, or reset local passwords with one-and-done efficiency. In addition, customizable reporting options make it easier to pre-extract needed information in the format that best supports your data integrity requirements.



"You can integrate with your LIMS through a web-based API, reducing potential for error and enhancing security. This in turn leads to improved data integrity and 21 CFR 11 compliance."

The option of web-based LIMS connectivity gives customers a solution that is more seamless and less file-dependent without the need for a bridge computer, noted Alex Kogan, product manager of the Growth Direct® System at Rapid Micro Biosystems. "You can integrate with your LIMS through a web-based API, reducing potential for error and enhancing security. This in turn leads to improved data integrity and 21 CFR 11 compliance."

In addition, the RMBNucleus™ Central Manager portal incorporates a web-based browser for flexible multi-system administration. It streamlines coordination of multiple instruments via integration with Active Directory, so customers can view all tests over the past 30 days at a glance, add users to multiple instruments in a single step, or send out timely alerts without physical access.

Result: a single-point, highly scalable solution that enables companies with multiple Growth Direct® System instruments to leverage QC automation for greater speed, productivity, and safety.





# RMBNucleus™: Taking the Growth Direct® System to a Higher Level of Integration



# COORDINATE

multiple instruments, remotely viewing orders and alerts for individual units.



# **MANAGE**

roles, status, and access for hundreds of system users as needed.



# **MONITOR**

thousands of samples in real time, with efficient recovery and cassette handling.

# **EVOLVING TODAY'S SYSTEM FOR TOMORROW'S NEEDS**

As customers pursue ambitious goals such as the "smart factory" vision of Pharma 4.0™, Rapid Micro Biosystems is committed to new digital innovations. To learn how we're evolving the Growth Direct® System of today into the future-proof QC ecosystem of tomorrow, visit our software page online or call us at +1-978-349-3200.

Or check out these related articles:

- Integrating Automated RMM for Digital Innovation
- McKinsey: Automated Testing Is at the Center of QC Evolution
- Pharma 4.0™ Mission Statement International Society for Pharmaceutical Engineering

