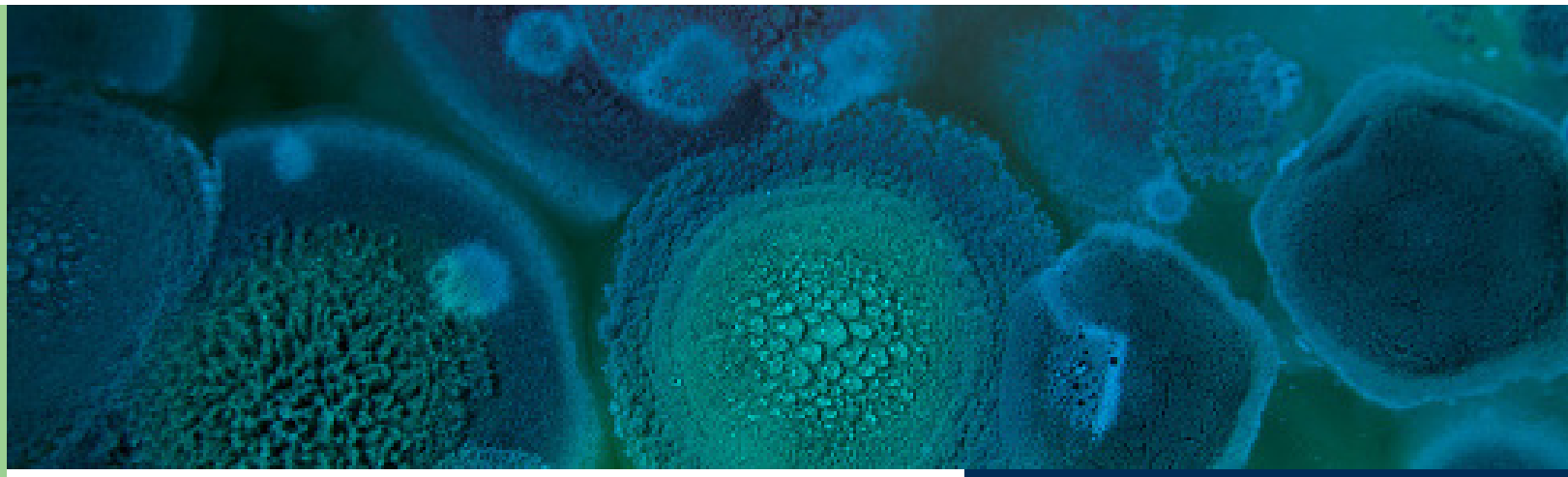


Making Your Automated QC Micro Lab a Reality

The "why" of automating QC labs is clear as pressures to improve speed, scale, and scope increase. But once you decide to automate, what steps can you take to plan an efficient installation and validation?

The industry's top manufacturing companies have started automating traditional compendial quality control processes to enhance their laboratory efficiency and release safe and effective products to market, quickly and with confidence. Understanding options for automating current quality control testing methods, exploring systems and platforms, is the first step in transforming the laboratory. Partnering with a vendor who can provide a comprehensive package offering services to support purchase, installation, implementation, validation, qualification, and hands-on training is a critical component when automating a quality control laboratory. Making certain the laboratory has the capacity, design, and is prepared for implementing a rapid microbial method (RMM) that is the right fit for your laboratory tests, requires upfront guidance and support from the choice vendor.

Is Your Quality Control Laboratory Rapid Ready?

Quality control microbiology continues to face increased demands for improved speed, scale, and scope to manufacture and release safe and effective products. As the industry strives to keep up, implementing and validating automated rapid methods for routine quality control (QC) microbial testing is the next step many manufacturers will take to meet these demands.

Rapid Micro Biosystems (RMB) partnered with our internal experts to provide real-world insights into the details of getting the laboratory ready for automation, specifically implementation of our rapid microbial detection system and software, Growth Direct®, to automate incubation, microbial detection, enumeration, and data management, to enhance laboratory accuracy, data integrity, and efficiency, with additional value-added benefits:

- Increases throughput
- Removes subjective, double-manual, plate count
- Eliminates human error
- Faster time-to-results
- Cost savings due to decreased variability
- Enhances traceability, audit capability
- Provides 21 CFR Part 11 compliant software
- Simplifies sample tracking with barcoding
- Improves data integrity
- Improves accuracy

Site Planning and Preparation

What role can the customer play in assessing site readiness?

The customer should have a project manager, or facilities manager, who can support and assist in managing the installation laboratory planning and preparation to facilitate any required changes and activities prior to the install and during the day of system installation.

Laboratory design, capacity, and available space should be addressed prior to purchase, ensuring the lab has the appropriate designated area (floor space, wall space, and ceiling height) to handle the assembled system, which measures approximately 241 cm high x 145 cm long x 99 cm deep (95”h x 57”l x 39”d) and weighs over a ton. Incorporate personnel’s space to access, navigate around, and perform testing on the system when measuring the designated area. During the install, confirm there is a cleared access route through the facility for the installers to deliver the system to the final location for assembly. Check access points such as, hallways, doors, elevators, to confirm a clearance, at least 6’ x 3’, for the larger disassembled parts.

Once the customer signs the pre-install agreement, the next step is to consult with a local utilities advisor to review the disclosed details on compressed air and power supply requirements for installing the Growth Direct® System. The utilities availability should be confirmed or required adjustments and laboratory site work should be completed, prior to the day of scheduled system installation.

Common Customer Expectations

Are there common goals customers have during system installation?

Our customers have common goals when considering rapid methods and the impact to daily operations such as cost savings, speed of batch release, and data integrity.

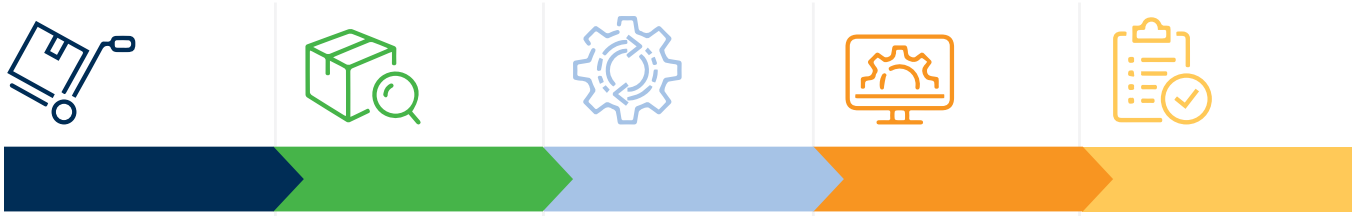
Historically, pandemics directly impact manufacturers causing supply and demand constraints for consumer products. The recent COVID-19 pandemic forced manufacturers to feel pressures to increase production and supply based on urgent and critical needs for pharmaceuticals, therapeutics, vaccines, disinfectants, personal protective equipment, and more. These demands shed light on why QC microbiology labs should be employing rapid automated microbial testing methods. Many industry leaders have already taken the initiative and implemented advancements towards QC lab automation. With rapid automated solutions in place they were able to effectively reduce hands-on testing, increased speed and efficiency for product release, and continue to operate and maintain target production during shortages.

With rapid automated solutions, you can reduce hands-on testing, increase speed and efficiency for product release, and continue to operate and maintain target production during shortages.

Simplifying the Installation Process

What are the core stages of an installation?

There are five stages for the installation of the Growth Direct® System:



Delivery
- Uncrate component
- Inspect for damage
- Record required serial numbers

Unpacking & Utility Verification

Test and verify requirements are met for:
- Supply voltage
- Compressed air

System Assembly
- Move system into place
- Install:
  – Computers
  – Top incubator
  – Power supply

Alignment & Calibration

System is powered on and mechanical robotics are adjusted:
- Going over imaging system
- Running test scripts
- Calibrating the incubators and rack configurations

Test Run Verification
- System covers installed
- 12-hour performance test carried out to ensure system is in proper working order

All stages are documented in a comprehensive installation record, ensuring the quality of a thorough installation, safety of the instrument, and continuing with a complete training for our customers.

Six Tips **for Easier Implementation**

1	**Measure** Verify that your chosen lab site has sufficient space, load-bearing capacity, and access to install the Growth Direct® System.	4	**Research** Learn about your new system beforehand by watching demos, asking questions, or checking with other users.
2	**Connect** Work with your utility or contractor to hook up electrical and compressed air systems before the installation team arrives.	5	**Train** Focus on training key users and lab staff who will be loading samples and operating the Growth Direct® System every day.
3	**Manage** Appoint an experienced project manager or liaison who can provide access to secure areas and handle capital equipment issues.	6	**Empower** Assign user rights to staffers who regularly operate the system so they can access troubleshooting features for fast, easy fixes.

Table 1. Helpful tips for QC labs adopting the Growth Direct® System

Ensuring a Successful Validation

After installation, what is next in the validation process?

Before routine use can begin, companies implementing our Growth Direct® System must validate their systems with stakeholders, quality assurance personnel, and external regulatory agencies.

The four key phases:

- **Installation/Operational Qualification (IOQ) –** This step concentrates on hardware and software components, confirming that they function according to the design specification. This includes the calibration and temperature mapping of the incubators.
- **Performance Qualification (PQ) –** Here we verify that the system's microbiological performance is comparable to the compendial method, testing system count accuracy and a variety of standard organisms according to applicable requirements of USP <1223>.
- **Time to Result Qualification (TTRQ) –** Once system performance is confirmed, we define the time required to establish a negative result. Test samples of standard USP and in-house slow-growing environmental organisms are prepared and run on the system at 30°C–35°C. Colony detection profiles from the Growth Direct® System are downloaded and analyzed, qualifying TTR as the point at which recovery of the slowest growing organisms is acceptable.
- **Method Suitability –** This final phase validates the new automated method against a specific product of interest, ensuring that there are no inherent characteristics interfering with organism growth or the detection technology of the Growth Direct® System.

Depending on the customer's internal quality team's availability, Rapid Micro Biosystems aims to complete the total validation process in four to six months.

What other services go into validation?

Rapid Micro Biosystems provides:

- Training services
- Documentation assistance
- Support for QC and QA Personnel

RMB will follow up after installation, providing a variety of support services:

- Testing at our reliability lab to improve system availability
- Advanced remote monitoring support
- Rapid response email alerts to prevent extended downtime
- Preventative maintenance visits to help ensure that the system stays up and running 24/7

If you have additional questions and would like to speak with an expert about our Growth Direct® System, contact us today.

CONTACT US

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