Quantifying the Economic Benefits of THE GROWTH DIRECT™ SYSTEM

Rapidmicro biosystems

In order to survive and thrive in an increasingly competitive economy, most pharmaceutical manufacturers have adopted lean initiatives within their production areas. But an often-overlooked area, Quality Control, has been left untouched by lean initiatives. Pharmaceutical companies can achieve maximum efficiency by evaluating and streamlining microbial quality control procedures using lean principles. In the past, this was viewed as difficult due to regulatory constraints but recent revisions to guidelines and requirements, such as TR33, have redefined and broadened the once narrow definitions making it feasible to comply and easier to validate new approaches that can deliver significant economic benefits.

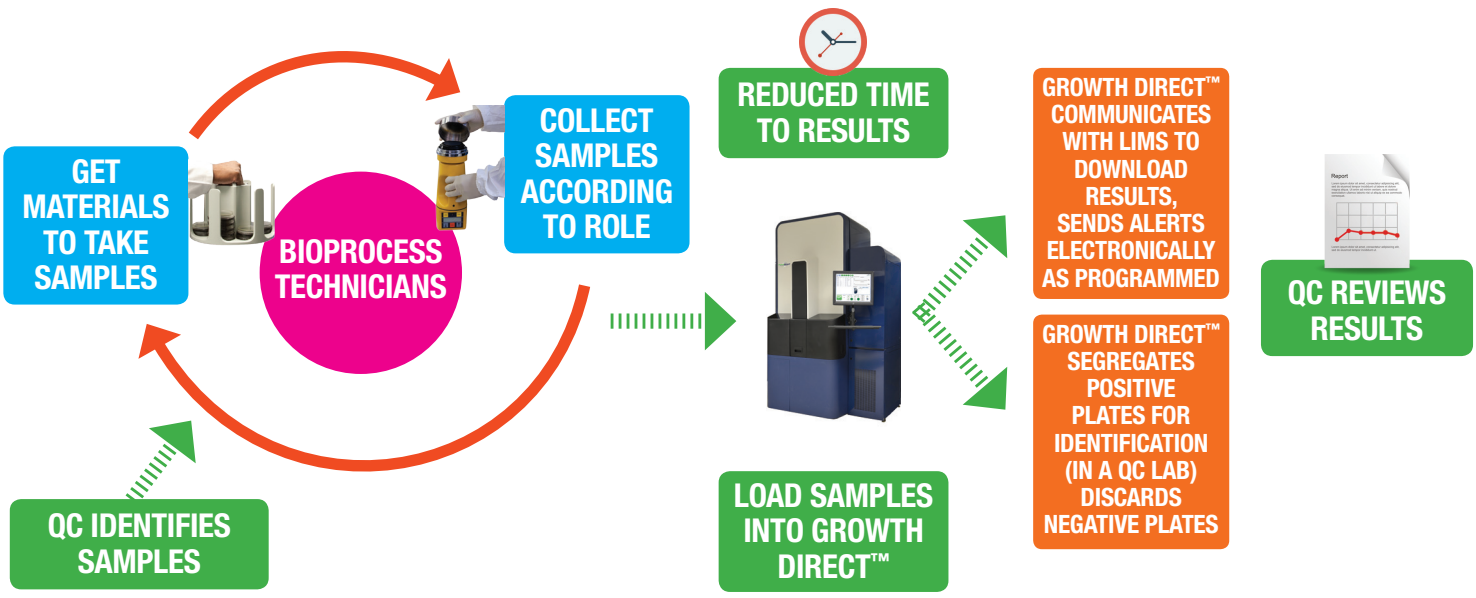
Since the traditional microbial enumeration methods are extremely manual, one of the most obvious and cost-efficient approaches is to automate microbial enumeration and detection. To achieve this, it's important not to add complexity by requiring all new procedures for sample preparation and enumeration. Unlike some rapid methods that would not be considered "lean", the Growth Direct™ System simply automates and accelerates the work microbiologists have traditionally done manually without changing the sample preparation, type of growth media or adding reagents or fluorescent tags.

Features and benefits of the technology include:

- The automation of all types of microbial enumeration testing including; water and bioburden, environmental monitoring and sterility tests
- High efficiency due to the reduced amount of hands-on labor needed
- Comparable sample preparation, reducing the need for retraining.
- Faster results due to the sensitive imaging technology that starts to see results in hours with final test results reduces the test time to 50% of the traditional test time
- Fewer out-of-specification (OOS) investigations due to the reduction in human error and a centralized audit trail for results, reports and operating conditions

Still, as beneficial as the Growth Direct™ System is for quality control personnel – and all other pharmaceutical stakeholders – quality control is rarely a focus for key decision makers. Changes to the current quality control processes may not have been considered as a clear, long-term ROI opportunity.

For quality control workers making the business case for rapid methods, here are a few of the most important considerations in quantifying the economic benefits of the Growth Direct™ System.



TESTING VOLUME

The Growth Direct™ System's ROI may vary from one company to the next, largely because of differences in testing volume, production processes requiring a QC result prior to moving to the next step, urgency of product release or extremely large inventories awaiting results to ship. Some manufacturers specialize in sterile products requiring a more intensive environmental, in-process and sterile testing program while other companies manufacture non-sterile products but in huge volumes. Other considerations include:

Raw materials.

Because individual ingredients must be tested before they're added to a batch, sites manufacturing a large variety of products may have numerous raw materials to test prior to production.

CMO or Pilot Plants.

Plants manufacturing numerous products on the same production line such as CMO's or Pilot Plants need to quickly clean and release their production lines to continue manufacturing.

In-process testing.

Complex manufacturing processes and high value products, such as biologics, often require multiple in-process tests. Products that require a number of in-process tests where production is stopped, awaiting those test results are an excellent opportunity for manufacturers to save on quality control time and labor.

Expansion of production capacity.

Whether they're increasing their volumes of existing products or creating new ones, expanding companies will need to consider their future testing requirements. New production lines require a "step-change" in testing volumes, particularly environmental monitoring. New labs, new equipment and additional full-time employees are a costly decision, and the Growth Direct™ System can yield significant savings on labor, space and expendable resources.

TEST TYPES

The Growth Direct™ System automates all major microbiological tests: water and bioburden, environmental monitoring and sterility testing. In general, the more of these applications that are automated, the higher the opportunity to save more on time and labor.

Each type of test delivers a unique return on investment. For example, traditional environmental monitoring testing tends to be 3 to 7 days in length, sometimes requires serial incubation, often represents the largest number of samples, and requires trending analysis. Much of the Growth Direct™ System's ROI in this case lies in the system's ability to automate the plate reading, reporting and trending analysis, sending an alert only when counts exceed the preset alert limits.

The major benefit of conducting sterility testing on the Growth Direct™ System is the speed of the results. In the case of a positive (sterility failure), the contamination will begin to show up in hours (exact time depends on the contaminating microbe(s)) allowing a site to take action and begin remediation efforts. Another time-saving step is that the contaminating colonies may be able to be "picked" directly from the cassette to go on to ID without having to waste additional days re-culturing. In the case of a negative sterility result (passing), the final test result is available in 50% of the time of the traditional 14 day test. So in 7 days, the product is available for sterility release. **When finished products are awaiting shipment, every day saved gets product to patients faster and reduces the financial impact of holding inventory.**

Overall, Growth Direct™ System users will need to analyze their unique products, site conditions and procedures to determine the impact to their ROIs. Issues of importance include:

Susceptibility of processes.

Some raw materials and manufacturing procedures are far more susceptible to contamination than others. Companies with large volumes of high-risk processes will likely see the greatest ROIs in due to time-savings and the automation of their bioburden and sterility tests.

Environmental testing program.

The complexity, sampling frequency, manufacturing schedule and number of production lines in the sampling plan will drive the savings realized by automating their environmental monitoring procedures.

Impacts of contamination.

Contamination events can have wildly varying impacts on productivity from one facility to the next. On production lines where an event can lead to days or even weeks of downtime, the Growth Direct™ System's quick turnaround and non-destructive tests will yield significant savings through faster, more targeted investigations.

GrowthDirect
EM • Sterility • Bioburden

CURRENT INVESTIGATION EXPENSES

Another benefit of the Growth Direct™ is that it prevents unnecessary OOS investigations through the elimination of human errors. To determine the ROI related to this benefit, users will need to calculate their current expenditures on unnecessary investigations. These are investigations that result from:

Sample mishandling.

Scheduled samples not taken, left behind or lost may not be recognized until days later leading to an investigation and a deviation. The Growth Direct™ helps technicians identify that an expected sample is missing so that action can be taken right away.

Incorrect incubation transfers.

Techs may transfer plates from one incubator to another at the wrong times, or not move the cassettes, triggering an investigation.

Tabulation/recording errors.

Even when every incubation time and temperature is correct –counting differences between technicians, transcription or key-punch errors cause investigations. The Growth Direct™ System prevents these errors through automated enumeration and reporting.

Finally, Growth Direct™ System users **are never left wondering what really happened to the samples. The system provides a complete audit trail of user interaction, sample processing, system operating conditions and the interim and final enumeration results.**

LABOR ALLOCATION

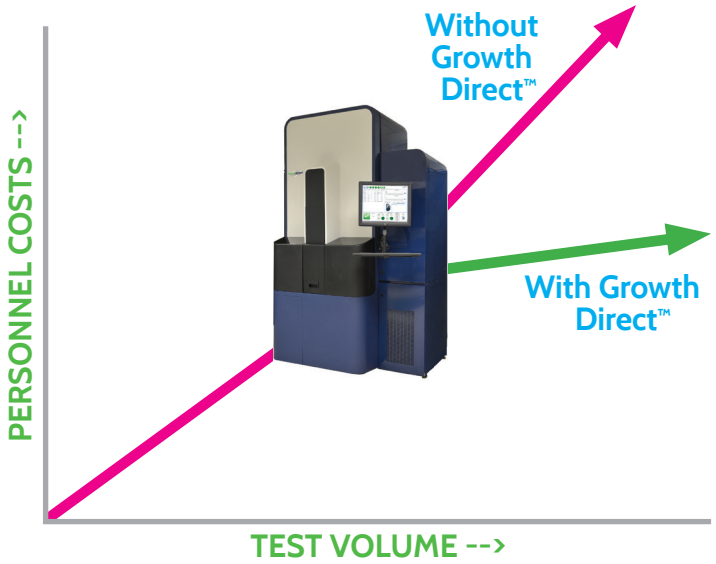
Automated enumeration also allows manufacturers to save hundreds of thousands of dollars per year in labor costs. When using the manual method, highly trained, highly educated microbiologists spend countless hours on incubation transfers, colony counts, data entry and other repetitive tasks. **With the Growth Direct™ System, they need only prepare sample cassettes using their current sample prep techniques and load on the system, the remainder of the work is done automatically.**

Much of the Growth Direct™ System's labor-related ROI will depend on the same factors as the ROI related to testing volume:

- Testing plan complexity
- Sampling frequency
- Manufacturing schedule
- Number of production lines

However, users will also need to examine the time and money they're currently spending training employees after OOS investigations and regulatory audits. **Eliminating errors through automation not only leads to more accurate and reliable results – it saves time and money on unnecessary training and re-training.**

Finally, implementation of the Growth Direct™ System may allow manufacturers to slow the growths of their payrolls. Companies that expand production volume and open new facilities will need to increase their testing volumes, as well, and automated enumeration removes the need for a proportionally larger quality control team.



SOFT BENEFITS

In addition to the Growth Direct™ System's quantifiable ROI, there are a number of intangible benefits current users have discovered. While these features may not sway decision-makers in and of themselves, they represent added value that can help to convince executives of the value of RMM technologies.

Paperless possibilities.

Through LIMS integration and the elimination of paper-based data entry, the Growth Direct™ System can be a major component in a company's initiative to improve the flow of information and speed of decision making.

Production line testing.

The Growth Direct™ System can be located in the vicinity of the manufacturing area, allowing for more efficient environmental monitoring.

Increased market share.

Faster, more reliable microbiological tests ultimately provide for more uptime, faster times to market and higher overall outputs.

Brand equity.

A contamination event on an FDA-483 can impact a company's public image tremendously. Through fast, reliable tests and targeted internal investigations, the Growth Direct™ System helps users to keep these events from happening in the first place.

Are you ready to reap the competitive benefits of a faster, more accurate and more labor-efficient quality control method? Discover the potential ROI of the Growth Direct™ System for your processes – contact us today.

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