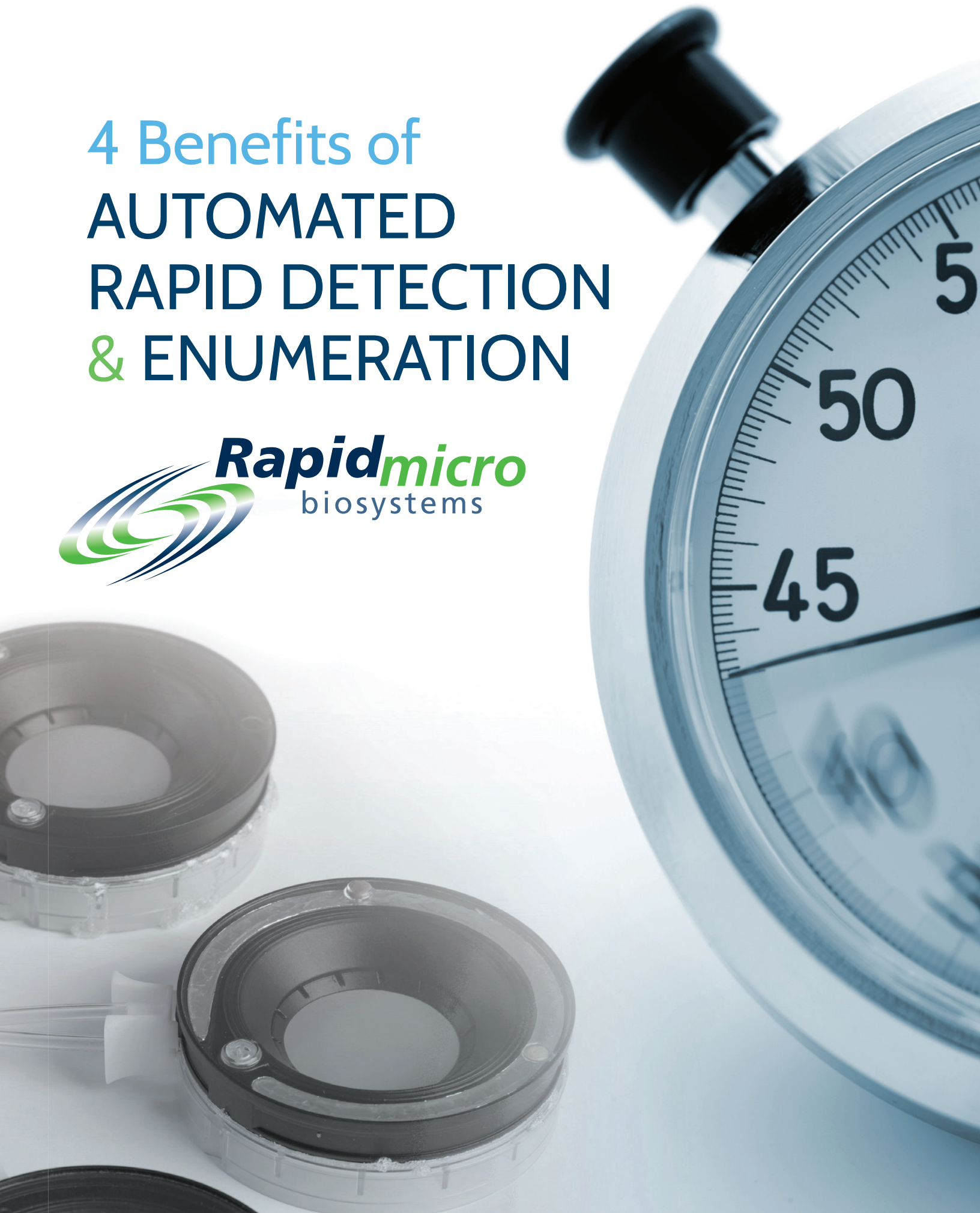


4 Benefits of AUTOMATED RAPID DETECTION & ENUMERATION





Competition in the pharmaceutical industry is tougher than ever, and few manufacturers can afford to compensate for inefficiencies with large inventories.

While other areas of pharmaceutical manufacturing have embraced lean manufacturing principles, the microbial quality control lab is still employing labor-intensive methods for testing.

Fortunately, leaner methods are now available. Automating microbial detection removes human labor – and error – from much of the quality control process, freeing up personnel and ensuring faster, more accurate results. Following are four of the benefits pharmaceutical companies can realize by implementing automated rapid detection and enumeration into their microbial quality control processes.

1

FEWER INVESTIGATIONS

With so many manufacturers operating on slim margins, minimizing out-of-specification (OOS) investigations is a top concern. Depending on their scope and complexity, each one can cost \$5,000 to \$20,000 in labor and materials. More importantly, investigations can delay the release of product batches. While it's critical to prevent contamination, investigations resulting from manual errors can erode product margins.

Fortunately, automation prevents most human error that lead to unnecessary excursions. Miscounts, misplaced plates and data entry errors are all but eliminated with an automatic system, ultimately creating fewer investigations. Microbiologists can spend more time on key issues and waste fewer resources on investigation.

In a contamination event, automatic detection provides more efficient and cost-effective investigations. Rapidly reported results and non-destructive imaging allow quality control personnel to start to perform root-cause investigations and identify the sources and causes of contamination earlier than with the traditional method. Instead of holding up entire manufacturing lines for days or weeks, the investigative team can quickly isolate and resolve problem areas.



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Finally, automatic enumeration streamlines the reporting process, making it far easier for microbiologists to analyze trends. By tracking data over time, variations in CFU counts, for example, can be identified and addressed.

www.rapidmicrobio.com



FEWER MANUAL ERRORS

The 100-plus-year-old manual method for counting cultures is rife with potential errors.

During incubation, plates can be misplaced, mislabeled or thrown out before they've been fully analyzed. During enumeration, miscounting can actually result in interim colony counts that are higher than final totals. Data entry is another area where there is an opportunity for transcription errors.



LOUIS PASTEUR

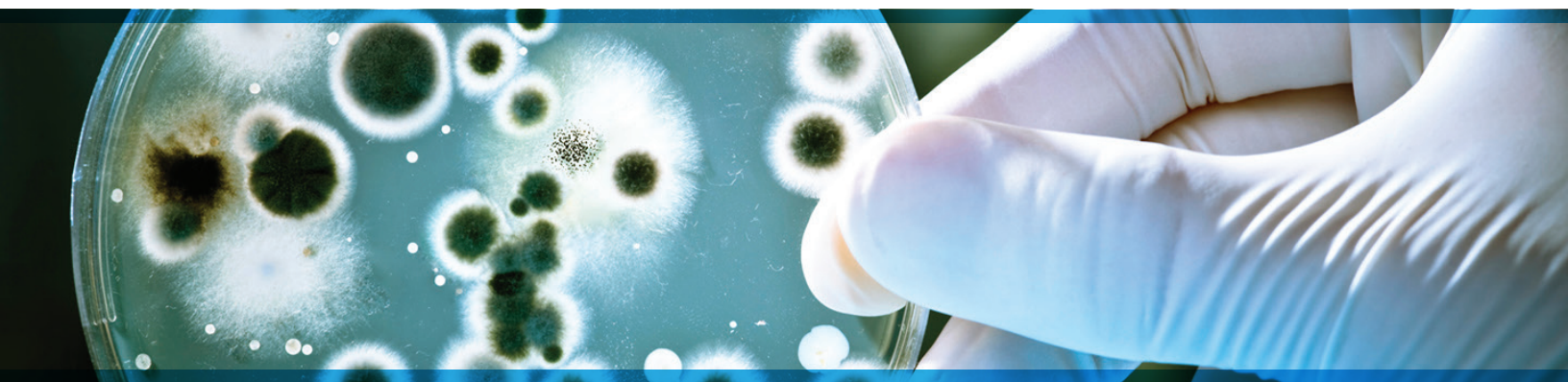
Founder of Modern Medicine



Automatic detection and enumeration drastically reduce these errors by assigning the imaging, plate transfer and data reporting processes to pre-programmed technology. Microbiologists prepare samples on barcoded cassettes, which can interface with existing laboratory information systems (LIMS). These cassettes are automatically sorted according to your testing protocol into on-board incubators set for into incubators set for specific times and temperatures and can be unloaded or transferred to the alternate temperature onboard incubator via automation.

Instead of relying on humans' error-prone eyes, automated rapid detection also involves digital imaging technology that detects and counts the autofluorescence of growing microbes. As the number of CFUs increases, the variability in counts between technicians increases. Using technology to detect and count colonies ensures accurate and consistent counting. By using a non-destructive detection method that uses no reagents, users can go on to identify the colonies in flagged cassettes without the need to re-culture. The interface between the system and LIMS also allows for automatic reporting, eliminating almost all data entry errors.

In contrast, the methods for improving accuracy with manual processes are prohibitively time-consuming and costly. Instruments can count and recount in seconds, but assigning additional personnel to perform plate count checks requires hours of additional labor. Discrepancies must then be manually resolved through further counting, and all results still rely on the naked eye.



Finally, rapid methods can drastically reduce the impact of staff turnover. Sample preparation is essentially the same as with the traditional method. Users require little additional training in the transition from manual to automatic processes.

RAPID RESULTS

In addition to increased accuracy, automated detection produces far faster results than traditional culture counting. Because colonies must grow to significant sizes to be detected by the naked eye, manual methods can take up to 14* days to produce useable data. On the other hand, digital imaging technologies can “see” microcolonies of as few as 100 cells, allowing for initial detection within hours and final results in about half the time of the manual method.

Automated enumeration allows for automatic data transfer, as well. Whereas manual processes require each count to be written on paper or entered one-by-one into LIMS, the results from digital imaging are instantly recorded and compiled. Quality control personnel can far more efficiently analyze hundreds or even thousands of samples and can quickly conduct further tests on cassettes with unacceptable levels of microbes.

When automated detection technologies are integrated with LIMS, alerts can also be sent immediately to quality control for early intervention. Instead of spending time on every sample, highly-trained and highly-paid personnel can direct their attention only to the positive samples and time-sensitive tasks. These rapid results ultimately lead to fewer investigations, less manufacturing downtime and fewer lost batches of product.

*Sterility Testing



4

LABOR EFFICIENCY

Automation and the elimination of redundant tasks are key in driving productivity savings.

Automated rapid detection and enumeration not only save money through increased accuracy and speed; they drastically reduce the workloads of all quality control personnel. Consider the following QC tasks:

SAMPLE TRANSPORT.

Traditionally, QC personnel have had to walk samples across massive pharmaceutical campuses and suit up before entering clean rooms. An Automated, rapid detection instrument can be located at the production site, and samples can be taken directly off the manufacturing line.

INTERIM TESTING OR SERIAL COUNTS.

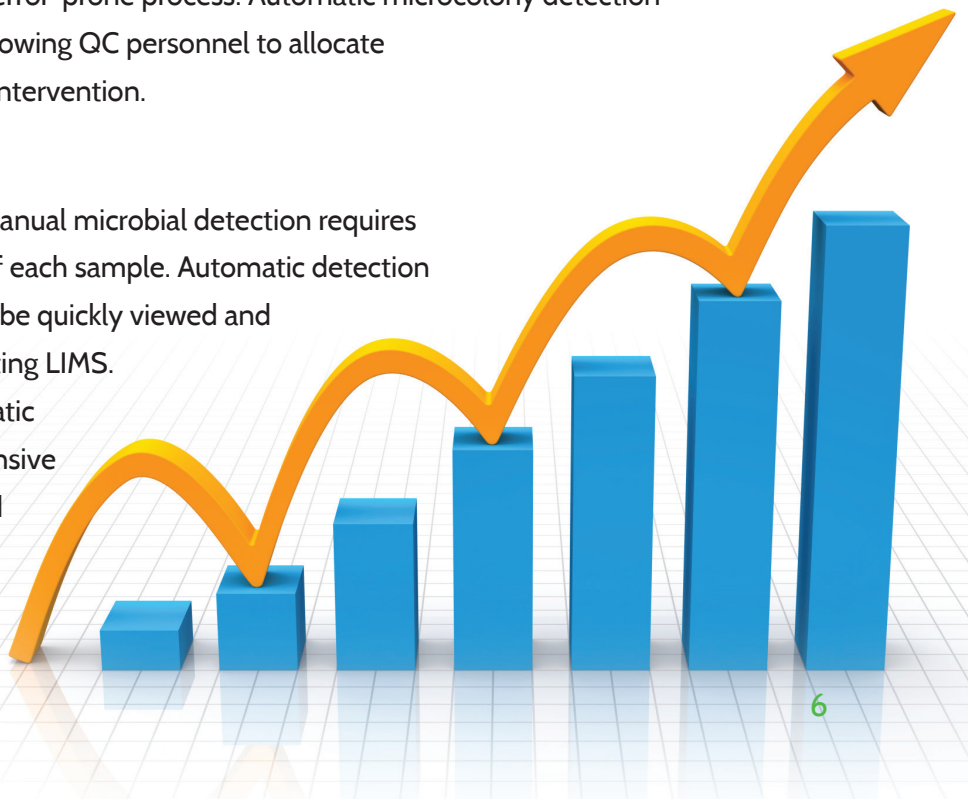
Manual methods often require the removal of plates for interim counts or for transfer to a different temperature. With automated rapid detection, the imaging technology performs counts every few hours, and the system will automatically move a cassette between incubators at the appropriate time interval. This saves hours of labor.

SAMPLE ANALYSIS.

Using current processes, microbiologists must manually count visible colonies on each plate – a time-consuming, tedious and error-prone process. Automatic microcolony detection eliminates this process entirely, allowing QC personnel to allocate more time to process design and intervention.

DATA ENTRY.

Even with a sophisticated LIMS, manual microbial detection requires technicians to record the results of each sample. Automatic detection creates instant records, which can be quickly viewed and analyzed through a variety of existing LIMS. Even in labs without LIMS, automatic enumeration produces comprehensive reports and generates alerts based on specified colony limits.



These efficiencies can create incredible value within a pharmaceutical organization. **By reducing the most time-consuming tasks associated with microbial detection, companies can save or reassign entire FTEs, reduce errors and OOS investigations and bring products to market faster than ever before.**

The Ideal System for Microbial Contamination Detection

The Growth Direct™ System enables the automation of the most common and time-consuming microbiology tests. With initial results in hours and final results in half the time of traditional methods, it can drastically reduce the time and money spent on tedious, manual enumeration steps associated with microbial quality control.



Three tests in a single instrument. The Growth Direct™ System automates testing for sterility, environmental monitoring, water and bioburden in the same instrument.



Non-Destructive results in half the time. The Growth Direct™ System leverages proprietary imaging technology to count growing colonies without the addition of reagents. Final results are typically produced in half the time of the conventional method.

Configurable Capacity. The system contains two separately configurable incubators with a total capacity of up to 700 cassettes. Robotics load, incubate and enumerate each sample, providing maximum throughput in minimal space.

Integration into LIMS. The Growth Direct™ System seamlessly integrates into existing laboratory information systems, accelerating the availability of sample data and eliminating data entry errors.

Actionable Alerts. Configurable action and alert limits allow QC personnel to respond to positives as soon as they're found. The Growth Direct™ also provides email and mobile alerts in the event of out-of-specification samples.

To learn more about the Growth Direct System,
contact **Rapid Micro Biosystems** today!



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