



## Accelerated Response Equals Accelerated Release

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Consumer care product manufacturers face mounting pressure to release their products quicker while simultaneously ensuring product safety and quality. As production timelines shorten and approvals are fast-tracked, you are still spending days waiting for the results of compendial testing... days of waiting and days of inventory investment sitting idle will not change unless you adopt newer, more efficient methods.

### Choosing an RMM is a Value Discussion

Not all rapid methods are created equal, and neither are suppliers. You need a rapid microbial method (RMM) to fit your company's needs, but how do you know you're making the right choice?

To aid the selection process, companies need to quantify the overall value using company-specific information as a good starting point to estimate potential savings, including the cost of capital, average value of daily finished goods, current days products are held for micro testing, and the volume of supplies used weekly. Using an RMM can help make faster business decisions regarding your company's large portfolio of raw materials and finished products and offer significant long-term value for your company.

A key facet of Good Manufacturing Practice (GMP) is quality control testing procedures, including RMMs. Raw materials and final product testing should be implemented as part of a GMP, addressing contamination risks earlier and faster. While conventional microbial limits testing has proven to be effective, its subjectivity prolongs the production cycle, delaying your time to market.

### Managing Production Efficiently

Some may argue that a microbial test should always provide enumeration and identification of contaminants. Where microbial presence is an uncommon event, your microbiologists are essentially "counting" zero colonies, which is where the economic benefits of RMMs are at their highest.

In the typical, controlled manufacturing facility, over 97% of products pass the final microbial limits test; therefore, a simple, rapid test which provides a presence or absence result is required for production. The small percentage of products that contain microbiological activity can be triaged through the RMM initial screen and can be selected to undergo further evaluation scrutiny against release criteria. By taking this route, exceptions are isolated and managed, allowing you to release a product up to six days faster.

If you are primarily encountering no colony growth in pour plate methods, you're utilizing time-consuming, resource-intensive methods to screen products. No time is wasted when a rapid, presence/absence primary screen indicates which products can be immediately moved out to distribution and which ones need a deeper look. Rapid microbial detection methods eliminate the subjectivity, allowing you to rapidly confirm whether a product is safe to release or not.

EVERY STEP OF THE WAY

## Range of Applications

Some rapid methods are perceived to have poor compatibility with consumer products, requiring labs to invest in several instruments. Choosing a rapid method requires the need to consider the range of raw materials, work-in-progress, and finished goods that can be tested with the selected system. The full economic benefits of RMMs cannot be recognized if the method cannot be applied to the majority of a company's products.

The "best" RMM for your company should be able to test a wide range of product matrices commonly seen in consumer care. Consumer care products have a variety of viscosities, some of which cannot be filtered. An RMM with flexible sample preparation can be used across your product lines and a variety of preservative systems or pH levels. When switching to an RMM, companies should not compromise the flexibility they have with traditional methods to make standard product accommodations.

Additionally, the detection system itself should not be subject to interference by particulate matter or product color. A good system allows your company to assess the majority, if not all, of its products such as shampoos and conditioners, lotions and creams, wipes, toothpaste, cosmetics, soaps and scrubs, gels and mousse, household cleaners, deodorant, and inks and dyes. Your company will benefit from using a standardized platform and maximize financial benefits through a broader application of rapid methods.

Look for RMMs that have already been validated and approved by regulators around the world for testing pharmaceutical products, which would make it an acceptable method for your over the counter (OTC) products as well. Replacing a traditional method with a single, harmonized platform with unmatched sample compatibility allows you to test a wide range of sample matrices, including varying viscosities, pH levels, particulate content, and structure.

## How Rapid is Your Method?

The "rapid" in rapid microbial methods refers to faster time to result, but an additional way to look at this concept is the throughput and ease of use, or the ability to process samples efficiently with minimal input. Some rapid methods may require extra steps to prepare samples, additional labor to deal with system complexity, or multiple systems to handle throughput requirements. The economic benefits of RMMs may be negated if it takes an unreasonable number of resources just to process samples with the rapid method.

Some RMMs offer the ability to process a large number of samples with minimal resource intensity, which refers to pure instrument throughput, personnel required to manage the system, and the sheer physical space necessary to accommodate the machine. Some systems will use a sample preparation technique that is as familiar as traditional agar plating methods, so additional labor is not needed to run the RMM.

You should also look for a system that can mitigate the risk of human error or subjective readings while being easy to validate and use. When integrated into a lean manufacturing process, testing raw materials or in-process formulations enables companies to detect contamination earlier and reduce production waste.

Finally, laboratory space is a major cost to consider. Some rapid methods, including the instrument itself and additional sample prep needed, require quite a bit of lab space. Some may require additional modules to accommodate testing volume. So, look for a system with a small footprint that can easily integrate into the existing bench space and can readily handle throughput requirements.

## Achieving Rapid Results

Getting products to market faster than the competition is a significant advantage. To match the ever-changing consumer market, frequent inventory turns and shorter production cycles are required to maximize profitability and reduce out-of-stock inventory.

A rapid microbial detection instrument is only as good as the reagents that power it. Utilizing reagent kits that can screen a wide range of products including toothpastes and dental rinses; face, hand, and hair washes; skin creams and lotions; household cleaners; and laundry detergents and fabric conditioners can help replace multiple individual systems with a single, harmonized platform. A simple “Yes/No” result makes the manufacturing environment more efficient thanks to a confident method of confirming product quality.

### **Considerations When Choosing an RMM Provider**

Selecting the right rapid method also means having an active relationship with a supplier who has the appropriate regulatory, validation, and scientific and technical support, or else it could be difficult to maximize efficiency. Finding a knowledgeable and dependable partner will ensure a smooth implementation and a streamlined product release cycle, enabling you to quickly reap the benefits of the rapid detection technology.

When assessing an RMM provider, you should consider the following:

What is their experience with similar products or materials in my industry?

Are the results reliable and beneficial?

What services do they offer? Is on-site installation and training provided?

Do they have experience assisting customers with regulatory compliance?

What validation support is available? Do they have adequate validation guides and documentation?

Has the system been accepted by the FDA and other global regulatory bodies?

While rapid micro methods offer significant value to microbiological labs, choosing the wrong system will cause frustration, delays, and waste; therefore, it’s critical to understand that your specific lab needs to choose an RMM that best provides rapid, relevant results while minimizing risk and optimizing resource allocation.

### **The Long-Term Outlook**

RMMs don’t just serve a valuable purpose for the lab. They can also benefit your entire organization, starting from the bottom up.

Think of it as a domino effect: RMMs deliver quick, definitive answers on whether your product is free from contaminants, enabling your company to make a more confident decision on whether it’s safe for consumers. This definitive decision enables you to streamline manufacturing of said product more quickly and get it to the market first. Being the first to market means a higher revenue share, which boosts your bottom line, enables you to really reap the benefits of rapid methods, and keeps your consumers coming back for more.

Traditional methods go against everything rapid methods stand for – they are subjective, slow, often lead to delays, and can grind your manufacturing/product release to a halt. Why take the chance on being trapped in the past when you can adapt the way of the future to boost not just your lab, but your entire organization?

### **How Can Charles River Laboratories Help You?**

We’ve purposely built our portfolio to bring you progressive products and services that deliver accurate, relevant, and reliable data to fuel confident decisions on product quality and contamination control. Our unique combination of Celsis® rapid microbial detection and Accugenix® microbial identification keeps your manufacturing operations running efficiently and smoothly, lowers your cost to manufacture, and protects your reputation.

Explore our portfolio of integrated services at [www.criver.com/personal-care-and-cosmetics](http://www.criver.com/personal-care-and-cosmetics).

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