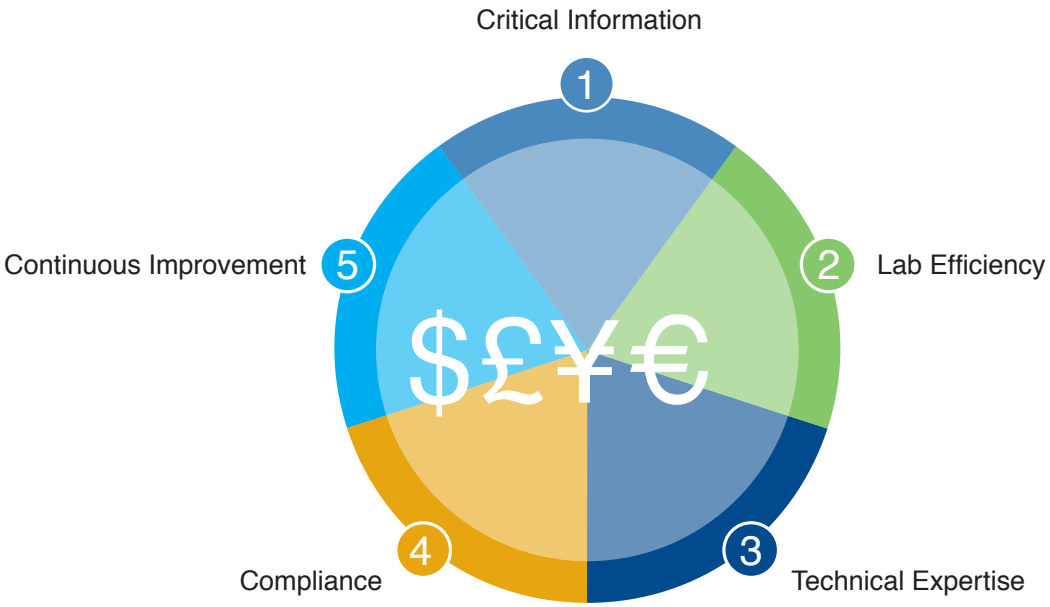
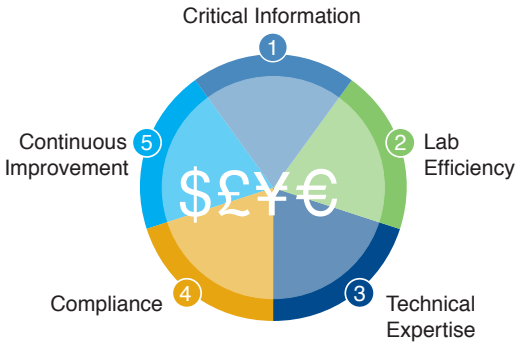


Considerations When Choosing a Rapid Method

There are many factors to keep in mind when choosing a Rapid Microbial Method (RMM) that's well suited for a Dairy, Beverage or Food manufacturer. Given the plethora of RMMs on the market and their widely varying capabilities, it is critical to understand exactly what your company needs to perform most efficiently and effectively. When this drives the purchase decision, you will be able to implement the system and realize a return on investment quickly.

Introduction

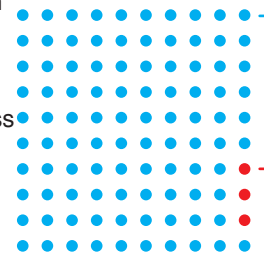
The key criteria in selecting RMMs share a common trait: a strong correlation to financial value. The more quickly an RMM can help you make appropriate business decisions regarding the majority of your product samples, the greater the financial value you will realize.



- The first consideration in selecting an RMM is the concept of Critical Information. How effectively does the method give you the information that you need to make a business decision fast, and does it deliver the financial return you are seeking? How can the system ensure reliable results?
- The second consideration is the Lab Efficiency of your RMM. No matter how fast the time-to-result you achieve with your RMM, the economic benefits may be negated if system throughput is compromised by capacitylimitations, labor intensity or physical space limitations. How much down-time is needed for maintenance of the system? Can it handle your daily workload while minimizing space requirements?
- The third consideration is the level of Technical Expertise offered by the provider. Can the system be implemented in your facilities around the world with the same level of support? What kind of assistance does the provider offer during implementation? How much experience does the provider have in providing rapid methods to dairy, beverage and food manufacturers? What resources does the provider have devoted specifically to support their ATP bioluminescence system?
- The fourth consideration is Compliance. Does the system offer features that enable you to comply with regulatory agencies/requirements? Will you be able to quickly locate result information during an audit? Can you access data generated at multiple sites from a single location? What level of security does the system provide for your result data?
- And fifth, consider the provider's Continuous Improvement. What improvements has the provider made to enhance their system over the years?

Consideration #1: Critical Information

Some have argued that a microbial test should always provide enumeration and identification of contaminants. This is not true in applications where microbial presence is an unexpected or rare event. Not surprisingly, it is within these same circumstances that the economic benefits of RMMs can be greatest. So, one should ask: "What results do I need to make a business decision quickly?"



Products test negative:
Rapid release
Reduced inventory and cost to manufacture

Products test positive:
Rapid response
Reduced contamination costs

Most of the time, your product is safe for release.

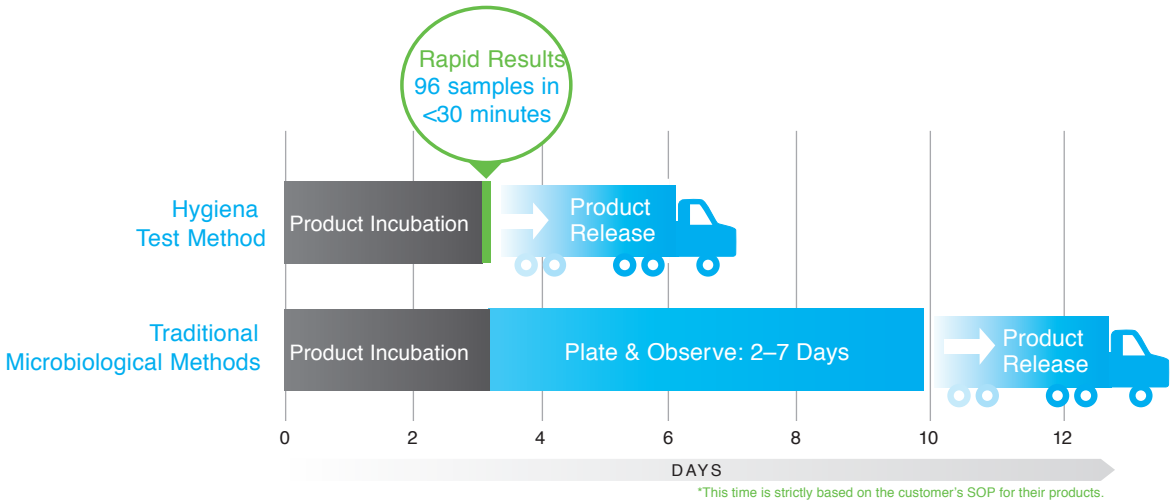
In the typical, controlled manufacturing facility, product passes the final microbial limits or sterility test more than 97% of the time. Therefore, a simple, rapid test that provides a positive or negative result is precisely what you need for the vast majority of your production. The small percentage of product that presents positive in the initial screen can undergo further evaluation against release criteria. That is how you 'manage the exceptions' and how, while you're doing that, the majority of your production is being released days faster—quickly and cost effectively.

Look for a SCREENING system that gives you a "yes" or "no" answer.

This speaks directly to the criterion of critical information: What information do you need in order to make a business decision that allows you to manage your production facilities most efficiently? While the exact percentages of contamination may differ for your company, utilizing time-consuming, resource-intensive methods to screen your products is a significant waste when a rapid, presence/absence primary screen will tell you what products can be immediately moved out to distribution and which few products need a second look.

Why plate and wait?

Reducing your product hold times even by just a few days can have a significant financial impact. A responsible RMM will utilize the same product incubation as your traditional method but replace the plate incubation with a rapid microbial screening test providing results days faster.



All products testing negative for contamination can be rapidly released with no additional testing necessary. Positives can be further evaluated against your release specification for enumeration and/or objectionable organism identification. And by selecting a non-destructive testing method, further identification work can be done using the incubated sample from the primary assay.

Reliability of results

Once implemented, dairy, beverage, and food manufacturers quickly become very dependent on their RMM and expect reliable results. If the results are inconsistent, confusion and uncertainty can lead to costly delays in product release and distrust in the system. How does the provider ensure consistent results are obtained from the system? A RMM that delivers consistent, reliable results will help you maintain minimal product hold times and maximize your ROI in the technology.

Consideration #2: Lab Efficiency

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

So, one should ask, "Can the rapid method process all of my samples without a major investment in space, people or additional instrumentation?"

Some RMMs offer the ability to process a large number of samples with minimal resource intensity—Which refers to pure instrument throughput, the need for personnel to manage the system, and the sheer physical space necessary to accommodate it. Some systems will use a sample preparation technique that is as familiar as traditional agar plating methods so that additional labor is not required to run the system. In addition, look for a system that can minimize the potential for operator error or subjective readings, and one that is easy to use and to implement.

System downtime for maintenance

Systems that are out of operation or require lengthy regular maintenance create delays in product release and thus impact ROI in the technology. It's important to consider how much time and effort will be needed to maintain the system. How much time is required to complete regular maintenance? How quickly will the vendor respond to critical issues with the system?

Laboratory space is valuable real estate.

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

Consideration #3: Technical Expertise

The third important consideration in selecting an RMM is provider support. Choosing a rapid method also means having an active relationship with a supplier who has the appropriate regulatory, validation, scientific and technical support. Without this, it is difficult to obtain maximum efficiencies from your investment. When looking for a vendor, choose someone whose experience and expertise is focused in rapid methods implementation, training and support.

Often, dairy, beverage, and food manufacturers do not have the ability to perform extensive application development studies in their manufacturing facility. An added benefit when selecting a rapid method provider is their ability to provide full service laboratories capable of performing challenge testing and method development.

Consideration #4: Compliance

The fourth consideration in choosing a rapid method is how the system allows you to be compliant with regulatory agencies. In today's world, dairy, beverage and food product manufacturers are increasingly interested in compliance capabilities so they can be ready if and when an audit occurs. A system that allows quick and easy access to all of their data is a huge benefit for manufacturers and simplifies the audit process. Larger manufacturers may also be interested in consolidating result data from multiple sites for easy access.

Can the system interface with your Laboratory Information Management System (LIMS)? How easily can data be accessed from multiple manufacturing facilities? A well rounded RMM system is one that offers extensive reporting features, broad access to secure data and customizable reports.

Consideration #5: Continuous Improvement

The fifth and final consideration in selecting an RMM is the provider's continuous improvement program. An investment in a RMM is a long-term decision with significant impacts on your company's productivity and supply chain. If the provider doesn't have a track record of innovation and system enhancements, they may not be able to meet your needs as your industry changes.

What track record does the supplier have in consistent improvement of their system? Are they dedicated to meeting the changing needs of the dairy, beverage and food industry? Do they have a state-of-the-art industrial sampling solution customized for large volume manufacturers?

Here are questions to consider:

- What is the provider's experience with similar products or materials in my industry?
- Are the test results consistent and reliable? Do they have claim support to back up their assertions.
- What other dairy, beverage and food manufacturers utilize their technology?
- Can they quantify the value of implementing a rapid method?
- What support services do they offer? In what regions of the world?
- Is on-site installation and training provided? What validation support is available?
- Do they have adequate implementation guides and documentation?
- How much of their resources are dedicated to rapid methods?

Finding the best RMM partner will ensure a smooth implementation and a streamlined product release cycle that enables you to realize the quality and financial benefits of the rapid detection technology.

Understanding the key criteria in selecting an RMM is critical and will enable you to choose a system that will best provide rapid, relevant results, while minimizing testing risk and optimizing your resource allocations.

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