charles river

Redefining RMM with Celsis®

Just being rapid isn't enough.
Your RMM needs to be the

Right Microbial Method.

Choosing a rapid method takes more time, energy, and money than ever before. And that's even before you consider what you'll need to implement it and ensure it works with your products and methods.

Not all RMMs are created equal, and neither are suppliers. So how do you know you're making the right decision for your products, your lab, and, ultimately, your company?

Celsis® rapid microbial detection for sterility

More than an instrument. A complete solution.

With the Celsis® detection platform for rapid sterility, we've created an unprecedented set of solutions, features, and options in a package that's designed for simplicity, not complexity. Instead of just providing an instrument with reagents and leaving the rest up to you, we've done the upfront work by partnering with other industry leaders to create a solution that makes perfect sense.

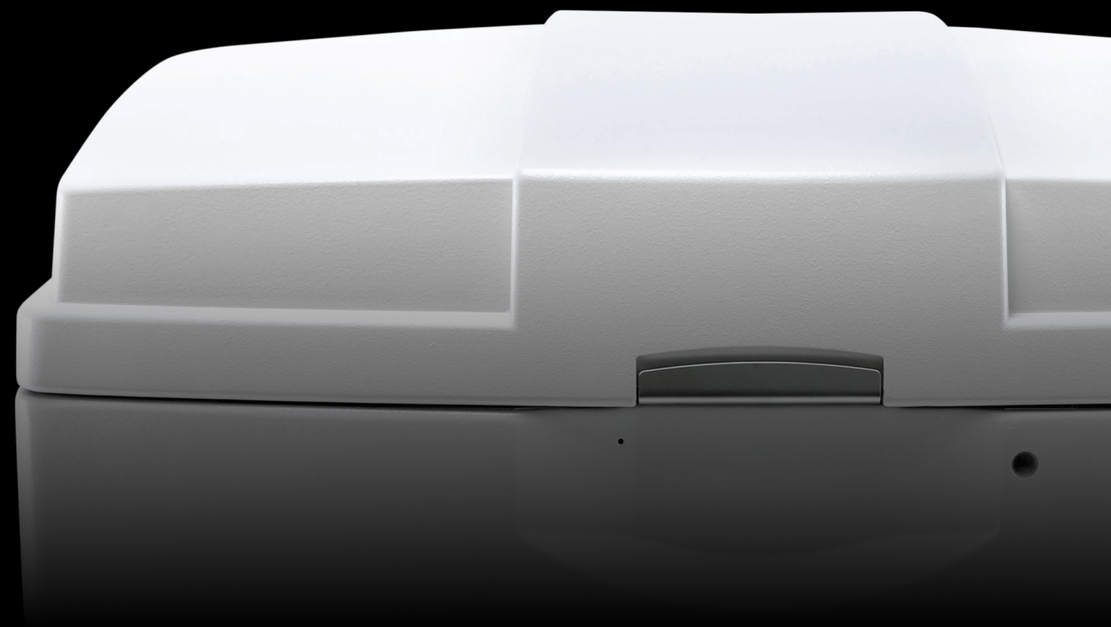
SARTORIUS

Pre-qualified, RMM-ready test consumables with Sartorius.

Pre-qualified sterility growth media with Hardy Diagnostics.

Industry-tailored services and support packages through Charles River.

No rapid detection solution has ever been put together like this before. Now that we've done it, it's hard to picture it any other way.



An RMM that covers all the bases

Goodbye status quo.

Historically, rapid methods have earned a perception as, single application instruments, requiring labs to invest in several instruments up and down their quality system. With an unmatched sample compatibility portfolio and application range, Celsis® can replace multiple individual systems with a single, harmonized platform to convert many traditional method-based QC assays with a rapid presence/absence assay.

From cell culture to sterility, and everywhere in between.

Cell culture

Celsis – 7 days

Compendial – 14 days

Raw materials

Celsis – 1 day

Compendial – 3-5 days

Chromatography

Celsis – 1 day

Compendial – 3-5 days

Water for injection

Celsis – 3-5 days

Compendial – 5-7 days

Purification

Celsis – 1 day

Compendial – 3-5 days

Final product sterility

Celsis – 6 day

Compendial – 14 days

Celsis® rapid microbial detection instruments

Built for simplicity.

We had only one goal: provide instruments that are as powerful as they are scalable and usable. All Celsis® instruments share the same impressive features, fluid ease-of-use, and regulatory-ready software design. With so many features in common, there's no need to compromise.

Easy integration into your current test protocols. Use your validated method. Eliminate days of incubation.

Objective results replace manual eye counts or visual turbidity checks with automated, instrument-based analysis.

Secure data integrity and control through on board, regulatory compliant software. Automated reporting. Multi-user management.

Sterility results in 6 days.

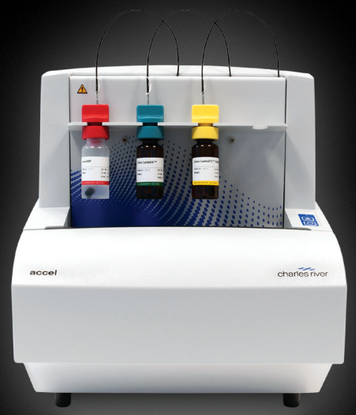
Bioburden in 24 hours.

Because finding nothing ultimately means everything.

Let your data work for you, instead of against you.

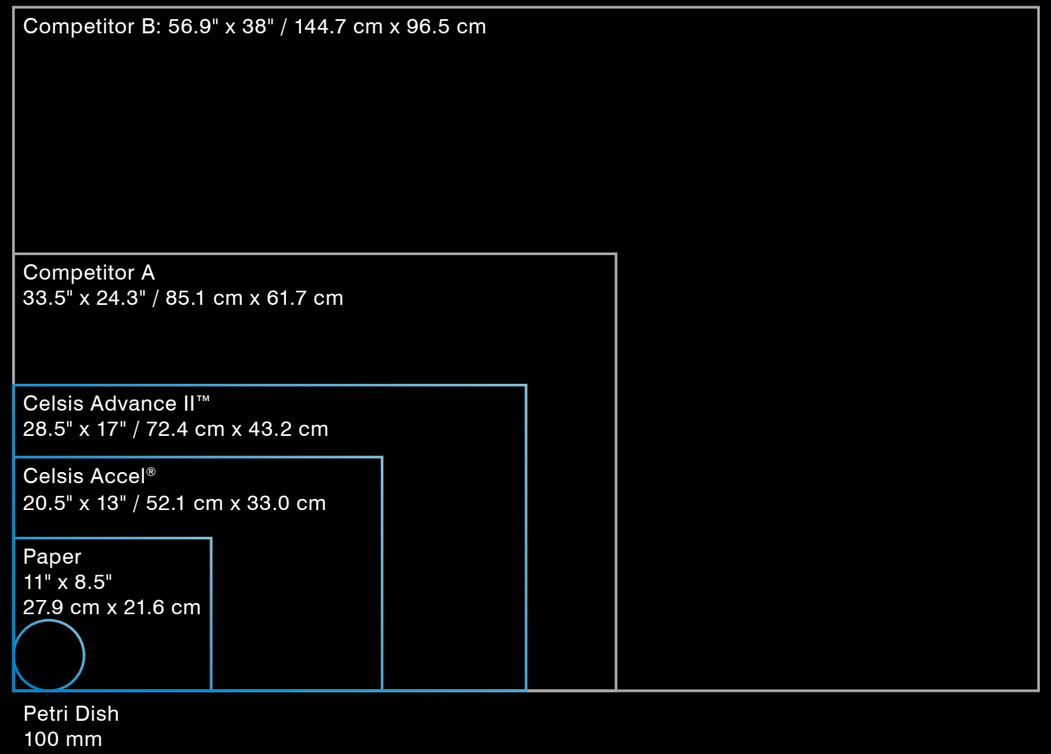
the Celsis Advance II™

the Celsis Accel®



Celsis® rapid microbial detection instruments

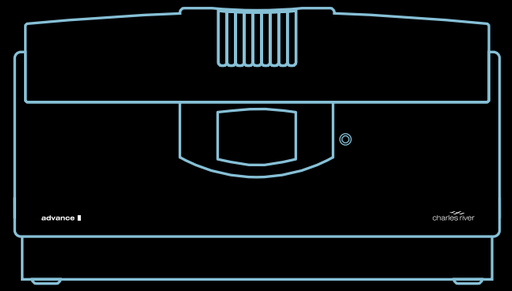
Expand your throughput. Not your floor plan.



the Celsis Advance II™

High capacity. High efficiency.

Provides the critical results necessary for critical decisions. Shorten production cycles. Detect contamination events sooner and respond even faster.

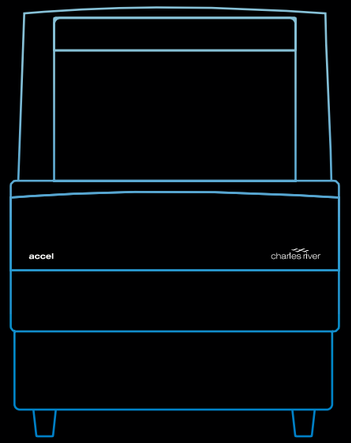


UP TO
120
assays
PER HOUR

the Celsis Accel®

Everything you need. Nothing you don't.

Provides the same high-performance detection and reagent compatibility as the Advance II for labs with workloads that are smaller, but no less important.



UP TO
30
assays
PER HOUR

Celsis® ATP-Bioluminescence

Robust Reagents. Rapid Results.

A rapid microbial detection instrument is only as good as the reagents that power it. Celsis® utilizes the most advanced class of adenosine triphosphate (ATP) bioluminescence reagents, unlocking new efficiencies for your QC workflow and a new level of confidence in the safety of your product.

Don’t settle for less. Charles River manufactures Celsis AMPiScreen® Pharma reagents to the same high-level quality you build into your own products.

Leveraging the same in-house expertise that produces our industry-leading FDA-licensed Endosafe® reagents.

Compatible with both Celsis Accel® and Celsis Advance II™.

Celsis AMPiScreen®

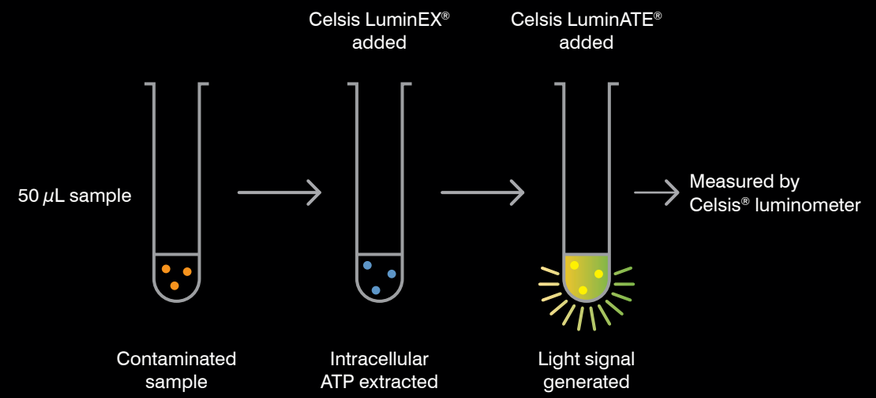
Amplify your Expectations.

Backed by 100 million years of R&D, ATP-bioluminescence is the gold-standard method for microbial detection, delivering reliable presence/absence results using the naturally occurring reaction. But why leave it all up to evolution?

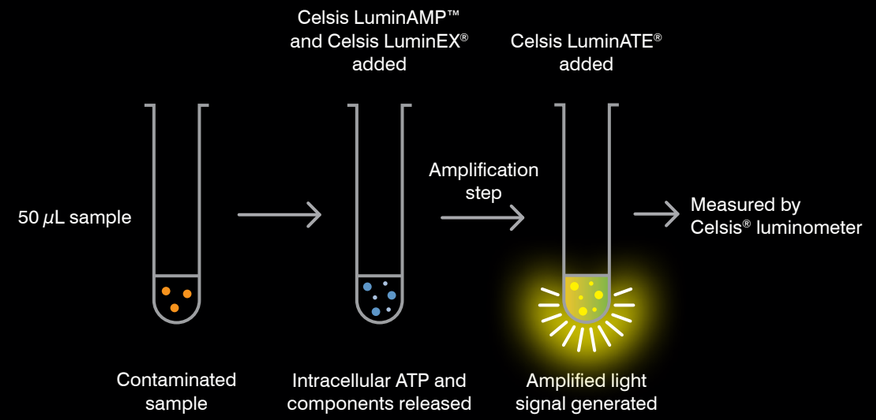
Celsis AMPiScreen® Pharma gives natural progress a push forward with an enzyme-catalyzed amplification step for an even faster time-to-result. With the addition of our proprietary reagent and automated amplification step, it takes just one minute to generate 40 times more isolated microbial ATP than was present in the sample – delivering more with less.

Why wait for log-phase growth, when you can be running exponentially?

Standard ATP-bioluminescence



Amplified ATP-bioluminescence



Introducing the Celsis Adapt™ Concentrator

Finally, a solution for cell culture samples.

The Celsis Adapt™ expands the utility of the Celsis® platform to cell containing samples for cell culture samples and cellular therapies. Utilizing a proprietary concentration and lysing process, the Celsis Adapt™ and accompanying reagent kit prepares samples for analysis on Celsis® instruments. Charles River has performed rigorous compatibility studies with commonly used cell lines in pharmaceutical manufacturing such as Chinese Hamster Ovary (CHO), Chicken Embryo Fibroblast (CEF), Mesenchymal Stromal Cells (MSC), and Human Embryonic Kidney (HEK).

Confidently answers the age-old question: Does it work with CHO?

Introducing Sartorius Sterisart® NF canisters

Pre-qualified to be worry-free.

Often, the biggest challenge when adopting an RMM is adapting your current and validated sample preparation methods to work with the new, alternative method. With Celsis® rapid detection, your sample preparation method is left nearly untouched.

We've partnered with Sartorius Stedim to provide an entirely pre-qualified closed-membrane filtration consumable ready for use with Celsis® instruments. Use a proprietary septum sample port to extract incubated sterility samples for analysis, preserving the closed system that was used to prepare it.

Nothing gets in unless you want it there. Rapid detection-ready from the start.

Pre-Qualified TSB and FTM Media from Hardy Diagnostics

Minimize variability. Maximize confidence.

While any manufacturer's media will be compatible with Celsis®, they aren't all optimized for it. We've partnered with Hardy Diagnostics to bring to market the first media pre-qualified for a rapid microbial method.

Each lot of Hardy media is tested on Celsis® instruments to ensure a consistent ATP-background from lot to lot, a release criteria that most manufacturers overlook and most RMM customers don't expect.

The highest level of control and performance. Lot to lot. Test to test.

Validation Services and Implementation Support by Charles River

The support you need from start to finish, and beyond.

As RMM adoption continues to increase, it's more important than ever that vendors become more than just instrument suppliers. They need to become partners: an organization to work alongside you every step of the way, supporting your alternative method. Not just at the point of sale at a single location, but all the way to routine use globally.

Celsis® Advantage Reports & Protocols

- Method Validation documentation
- Protocols for Testing in Presence of Product

Celsis® Complete Validation & Reports

- Method Validation documentation
- cGMP Validation Testing in Presence of Product

Installation Support and Ongoing Training

- 3 Day Initial Installation and Training
- 1 Day Supplemental Training

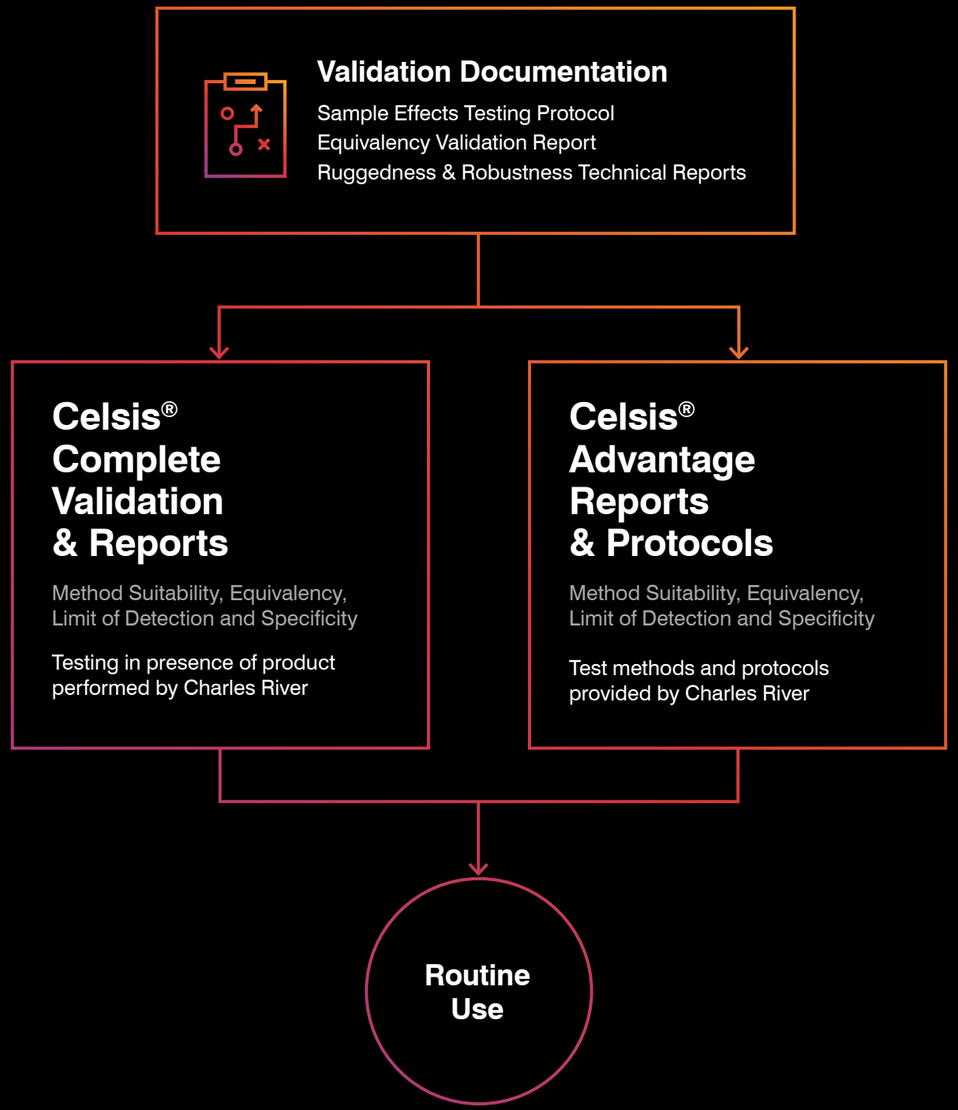
We've harnessed the power of our global support network, our entire portfolio, and our industry-proven expertise in alternative, rapid methods to provide custom tailored support options depending on your validation strategy, your capabilities, and your product.

Celsis® Complete & Celsis® Advantage Validation Support Packages

Streamlining the validation journey

Two support packages are available to demonstrate validation parameters described by United States Pharmacopeia (USP) <1223>, European Pharmacopoeia (Ph. Eur.) 5.1.6, and Parenteral Drug Association Technical Report (PDA TR) 33, providing a complete solution that reduces the time from installation to routine use of your Celsis® rapid detection system.

Simple answers to a complex question.

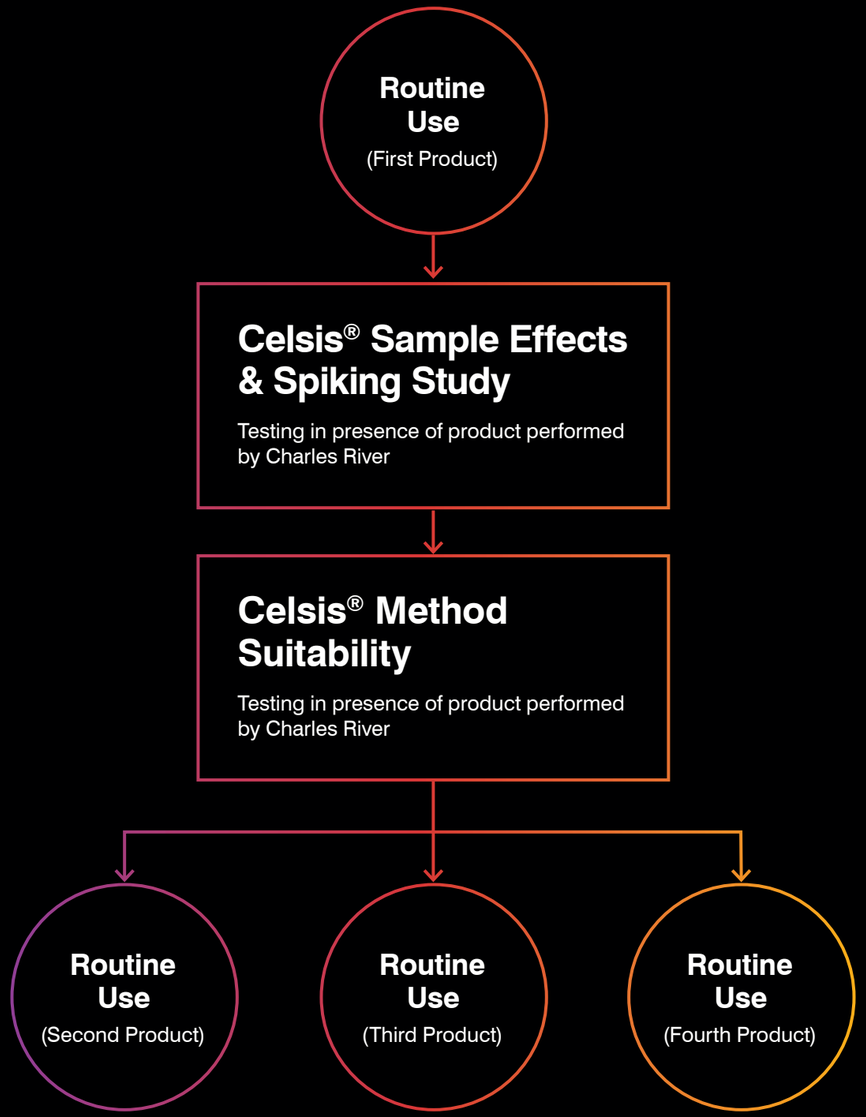


Validation optimization using Celsis®

Ready to work. Just add products.

For additional products, outsource all of the testing to us or perform on your own with the testing protocols included in your original Charles River validation package.

As easy as rinse and repeat.



Charles River Microbial Solutions

Your success is our success, whichever way you want it.

Complete RMM Solutions.

What does yours look like?

the Celsis Accel®
Product Code: 7460288

the Celsis Advance II™
Product Code: 7456004

Celsis Adapt™ Concentrator

Product Code: AD9000

Celsis Adapt™ Cell 100 Assay Reagent Kit
Product Code: AD1420

Celsis AMPiScreen® Pharma Reagent Kit

400 Assay Reagent Kit
Product Code: RST400

Sartorius Sterisart® NF for Celsis®

Celsis® Qualified Sterisart® NF Septum with 4 cm dual-needle
Product Code: 16466CR-GSD

Celsis® Qualified Sterisart® NF Septum with 5.2 cm needle
Product Code: 16467CR-GSD

Hardy Diagnostics Media for Celsis®

Celsis® Qualified Hardy Diagnostics Tryptic Soy Broth, USP, 100 mL Septum Top Glass Vial
Product Code: CM1010

Celsis® Qualified Hardy Diagnostics Fluid Thioglycollate Medium, USP, 100 mL Septum Top Glass Vial
Product Code: CM1015

Charles River Implementation and Validation Support

Celsis® Complete Validation & Reports

Method Validation documentation for Equivalency, Specificity, Robustness, Ruggedness, and Limit of Detection.

cGMP Validation Testing in Presence of Product for Method Suitability, Equivalency, Limit of Detection, and Specificity.

Product Code: VAL6000MF

Celsis® Advantage Reports & Protocols

Method Validation documentation for Equivalency, Specificity, Robustness, Ruggedness, and Limit of Detection.

Protocols for Testing in Presence of Product for Method Suitability, Equivalency, Limit of Detection, and Specificity.

Product Code: VAL6100MF

Celsis® Validation Testing Services for Additional Products

Celsis® Spiking Study
Product Code: VAL2400PH

Celsis® Sample Effects
Product Code: VAL2500PH

Celsis® Method Suitability
Product Code: VAL5000MS

Installation Support and Ongoing Training

Celsis® 3 Day Initial Installation and Training
Product Code: TS0003

Celsis® 1 Day Supplemental Training
Product Code: TS0001

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