

## Celsis Amplified-ATP Technology

Amplified-ATP technology in a rapid, absence/presence primary assay provides the critical information you need to respond immediately to the occasional lot that carries bioburden while quickly and efficiently releasing the majority of your production run.

With Celsis, you get the fastest release time for the vast majority of your goods, and can manage any exceptions more cost-efficiently and with less waste. That's good for your department, good for your facility and good for the planet.

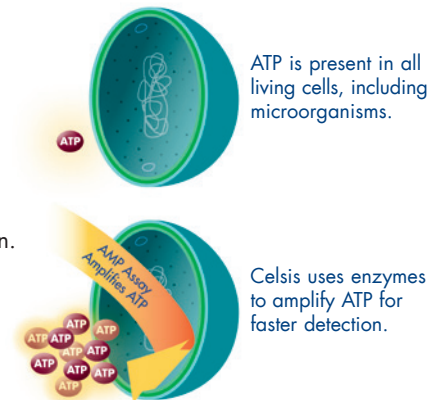
The ideal lean solution for rapidly testing finished goods, in-process samples and raw materials for microbial contamination.

Technology exclusively from Celsis is available to amplify the ATP bioluminescence assay—the industry standard in rapid detection—generating reliable and accurate results quickly for microbial limits (MLT) and sterility testing. Negative growth is confirmed within 24 hours for MLT or, for sterility testing, in less than half the time of traditional methods. Amplified-ATP technology is also 25–50% faster than the standard ATP assay.

ATP bioluminescence provides an effective approach to microbial testing but is solely dependent upon microbial growth to achieve sufficient levels of ATP for detection. While all living organisms contain ATP, they contain other compounds as well. The Amplified-ATP assay is not constrained by the limited amount of metabolic ATP in the organism. Instead, it produces additional ATP by using an enzyme-catalyzed reaction.

After just 25 minutes, the amount of ATP in the sample can increase 1000 fold, making it readily detectable in a shorter period of time. The amplified ATP is then detected and measured using the traditional luciferase reaction.

With validated systems running millions of assays in over 65 countries, Celsis is proven technology, effective on thousands of different product types. Protect your brand and your bottom line while saving time, reducing lab waste and ensuring product safety with Celsis rapid detection systems.



Smart science for smart business™

# Celsis Rapid Detection System Featuring AMPiScreen Technology



## AMPiScreen Reagent Kits

Feature proprietary enzymes, used in combination with the Advance and Accel instruments and software, to minimize time to detect microbial contamination.



Celsis Advance II™ System



Celsis Accel™ System

## AMPiScreen Reagents

- Widest range of testable products, including filterable and non-filterable, viscous, high or low pH, immiscible, highly-pigmented and turbid samples
- Validated on a wide array of raw materials, in-process formulations and finished goods
- High Signal/Noise ratio delivers more distinctive positive results in cases of low-level contamination
- Convenient, single enrichment for Limits testing of bacteria, yeast and mould with less waste
- Non-destructive assay allows for further testing, if needed
- Proprietary reagent kits formulated to match different sample requirements
- Reagents manufactured by Celsis in our ISO-certified facilities

## Luminometers

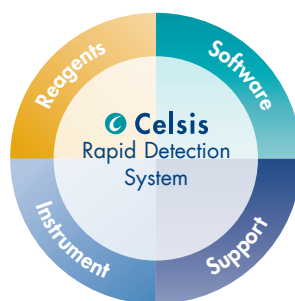
- High system throughput and offline incubation allows for testing of up to 120 or 30 or samples per hour
- Up to four variable-volume reagent injectors offer greater automation for improved accuracy, less sample handling and increased "walk-away" time
- Simultaneously tests multiple sample batches or protocols in a single run
- Small footprint conserves valuable counter space
- Manufactured to ISO standards
- Reduces lab waste by reducing the use of media, plates and jars; saves water and energy

## Software

- User-friendly system with color-coded graphical interface
- Delivers clear, non-subjective, actionable results
- Developed exclusively for industrial microbiology laboratories
- Customizable security levels
- Export data to common applications including Excel and Access
- Ability to lock the application with a single mouse click in order to ensure an uninterrupted run
- Validated on Microsoft® Windows® operating systems
- Allows for compliance with 21 CFR Part 11 and Annex 11 requirements

## Service & Support

- Unparalleled 24/7 global technical and scientific support
- Complimentary Installation and Operation Qualification (IQ/OQ), training and validation protocols
- Convenient Celsis in-house labs for application development and validation support
- Optional validation services through Celsis or our CGMP lab partners
- Global team of experienced Customer Service and Technical Support Representatives
- Regulatory compliance experience and support, including drug master files (DMF) accepted by the FDA, for microbial limits and sterility testing and Technical Reports to support regulatory submissions in other countries



For more information about Celsis, visit [celsis.com](http://celsis.com), call +1 312 476 1282 or email [RDinfo@celsis.com](mailto:RDinfo@celsis.com).

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