



## MICROBIAL SOLUTIONS

# Celsis AMPiScreen® Pharma Reagents for Rapid Microbial Detection

## Celsis AMPiScreen® Pharma reagents

- Results up to 75% faster than traditional methods
- Confirm the absence of microbial contamination for:
  - Raw materials
  - In-process bioburden
  - Microbial limits
  - Final sterility testing
- Flexible kit configuration
- Simplified reagent preparation
- Compatible on both the Celsis Accel® and Celsis Advance II™

Adenosine triphosphate (ATP) bioluminescence provides an effective approach to microbial testing but is solely dependent upon microbial growth to achieve sufficient levels of ATP for detection. The Celsis AMPiScreen® Pharma reagent line can rapidly detect the presence of ultra-low levels of microbiological contamination up to 50% faster than traditional ATP bioluminescence. The inherent subjectivity of manual enumeration or visual growth confirmation is removed with a confident "Yes/No" answer, providing critical information whether to release or hold a product.

The Celsis AMPiScreen® 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 and an additional instrument-controlled amplification period to optimize the detection of microorganisms.


Based upon a proven detection method, Celsis AMPiScreen® products amplify low levels of contaminant ATP present in a test sample that are then easily detected by bioluminescence within Celsis® instruments.

## Reaction Principles

The fundamentals are simple, yet powerful. Celsis® rapid microbial detection technology is based upon a naturally occurring, ATP-bioluminescence reaction, which also provides the characteristic glow of fireflies.

Known as the luciferin-luciferase reaction, it occurs when the luciferase enzyme converts luciferin into oxyluciferin to produce light. Only when ATP is present will this reaction occur. Since ATP is present in all living cells, including prokaryotes, it can be used as a marker for contamination if a sample should not, under normal conditions, contain ATP.

EVERY STEP OF THE WAY



The standard ATP bioluminescence detection principle, used in Celsis LumiScreen™ reagents, reproduces the luciferin-luciferase reaction using reagents, where the presence of ATP molecules, derived from microbial contamination, generate light that is detected by a Celsis® luminometer. If no microbial contamination is present, the reaction does not occur and no light is produced.

Traditional methods rely heavily on lengthy incubation periods to achieve visible growth, for colonies to grow large enough for confident enumeration in microbial limits, or for unambiguous turbidity in sterility testing. ATP-bioluminescence based rapid detection can reduce these incubation periods by 50%.

### **Amplifying ATP Gets Results Even Faster**

Using amplified-ATP technology, results can be achieved 25-50% faster than traditional ATP bioluminescence, yielding 75% faster results compared to the traditional method. While all living organisms contain ATP, they contain other compounds as well. The Celsis AMPiScreen® 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 to drive the production of ATP, from its precursors, and then activates the ATP-bioluminescence reaction.

After just 25 minutes, the amount of ATP in the sample can increase 1,000 fold, making it readily detectable even with a shortened incubation step. The amplified ATP is then detected and measured using the traditional luciferase reaction.

Thus, the total amount of ATP can then be more readily detected and measured using ATP bioluminescence. Given the ability of enzymes to affect reactions without being depleted or changed, it is possible to generate almost unlimited amounts of the reaction's products. Since ATP is one such product, and the reaction is essentially linear in nature, the longer the reaction is allowed to proceed, the more ATP is generated. This strengthens the bioluminescent signal and, therefore, the assay's sensitivity.

### **Flexible Kit Configuration**

The 400 assay kit configuration affords convenient and efficient reagent usage and minimizes wasted product for both small and large manufacturers and varying throughputs. User-centric packaging allows for simplified and economical storage, differentiation, and easy access for day-to-day use.

### **Simplified Reagent Preparation**

Celsis AMPiScreen® Reagent kits are comprised of three separate reagents, Celsis LuminAMP™, Celsis Luminex®, and Celsis LuminATE®. Each reagent is essentially ready to use off the shelf, requiring only a simple rehydration step of Celsis LuminATE® with its included buffer. Reagents are then loaded into the easy access reagent holders on Celsis® luminometers.

### **Universal Instrument Compatibility**

Celsis AMPiScreen® reagents are universally compatible with all Celsis® luminometers. The Celsis® luminometer controls the addition of reagents, the timing of the reaction, and the recording of any generated light signal, reported in relative light units (RLUs).

### Cross-Reagent Compatibility

A single instrument can run both Celsis AMPiScreen® and Celsis LumiScreen™ reagents in back-to-back runs. The instrument's reagents can be easily swapped followed by a simple rinse, wash, and prime process, all guided by on-screen prompts. Specific protocols can be pre-defined and saved using Celsis® instrument software for varying product types and reagents.

### Storage Conditions

Reagent kits are stored at 2-8 °C when not in use. Once reconstituted, the stability of the reagents is 2 working days (up to 8 hours per day) at room temperature between 18-23 °C. Unused reagent can be stored at 2-8 °C for up to 4 days in between the two room temperature usage periods.

### Maintenance and Support Consumables

The use of Celsis AMPiScreen® reagents in an instrument will not affect the use of universally compatible set of support reagents (Celsis® ATP Positive Control, Celsis® Daily Wash & Rinse, and Celsis® Monthly Maintenance & Cleaning kits).

### Quality Manufacturing

Charles River manufactures its reagents to the high quality standards pharmaceutical companies strive to meet in their own products. Celsis AMPiScreen® products leverage the same expertise and experience used in producing industry-trusted Endosafe® reagents.

## Celsis® Rapid Microbial Detection

Product	Reagent Kit Components	Code
Celsis AMPiScreen® Pharma	<b>400 Assay Kit</b>	
	8 x 8.6 mL vials Celsis LuminAMP™	
	8 x 8.6 mL vials Celsis LuminEX®	
	8 x 50 assay vials Celsis LuminATE®	
	8 x 8.6 mL vials Celsis LuminATE® Buffer	RST400
Support Reagents and Consumables	<b>Celsis® Daily Wash &amp; Rinse</b>	1290142N
	<b>Celsis® Monthly Maintenance and Cleaning Kit</b>	92828
	<b>Celsis® ATP Positive Control Kit</b>	1291483