Rapid contamination testing for cell culture and cell-based samples: A new standard in the pharmaceutical industry

THE NEED FOR rapid microbiological methods (RMMs) for quality control is not new. The pharmaceutical industry has made slow progress adopting them over the last decade, with a sharp spike in uptake within the last two years. To resolve new challenges caused by the COVID-19 pandemic, contend with supply chain issues and release therapies faster to patients, the industry turned toward RMMs as a solution.[1] The industry paradigm has shifted from rapid methods being a "nice to have" option to a model in which they are critical, if not necessary, for continuous operation and the ability to release products safely.

However, the industry has a growing need to expand the application of their rapid methods across their entire quality control (QC) strategy and many on-market RMMs have failed to support this. Certain technologies have inherent limitations preventing compatibility with a wide variety of testing methods and sample types. These technologies may support either direct inoculation or membrane filtration methods, but not both. They may also be destructive to the organism, holding back investigations that depend on identification.

A particular challenge has been the presence of cells in samples, which introduce interference for both RMMs and many traditional tests like sterility. Moreover, while the COVID-19 pandemic put a spotlight on the need for faster contamination detection and release for operational efficiency, the rapidly growing cellular and gene therapy industry is also in need of faster results when releasing short shelf-life products safely to patients. The need is clear for RMMs to provide multi-point solutions, not just for a single application, but for utility up and down the manufacturing QC process.

The Celsis Adapt™ concentrator system now addresses this need for pharmaceutical, biotechnology, cell, and gene therapy manufacturers by expanding the use of the Celsis® ATP bioluminescence platform[2] to test samples containing cells. As an accessory instrument for the Celsis® platform, the Celsis Adapt™ employs a lysis and concentration protocol to effectively remove the interference of cells, dissolved solids and excess liquid from quality control samples while retaining bacterial, yeasts and fungal contaminants. Results can be obtained in just seven days for cell-containing samples, reducing the time-to-result by more than 50 percent in many cases.

The Celsis Adapt™ has undergone rigorous testing, both by Charles River and in collaboration with industry-leading manufacturers, to demonstrate compatibility with a wide range of manufacturing cell lines, including:

- CEF (chicken embryo fibroblast)
- Mesenchymal stromal cells
- CHO-K1 (*Cricetulus griseus*, Chinese Hamster ovary)
- CHO-DG44
- CHO-BHK21 (Baby hamster kidney cell)
- HEK-293 (Human embryonic kidney)
- HeLa (Human).

Moreover, the same technology can be employed for release testing of advanced therapy medicinal products[3] in as little as three days using a risk-based approach. This means manufacturers specialising in each of these therapies, or those with product portfolios which span them, can finally implement a single, harmonised rapid detection solution across their quality system, their portfolio and even their global network of facilities.

Compatible with both the Celsis Accel® and Celsis Advance II™ instruments, the Celsis Adapt™ further unlocks the advantages of utilising a single in-house RMM to achieve the critical results necessary to ensure patient safety, regardless of the sample type.

To learn more about the Celsis Adapt™ and the Celsis platform, access technical resources, read success stories from the industry, or to request a quote, please visit **criver.com/adapt**.

References

1. Celsis Rapidly Becoming Pharma Industry's Go-To RMM | Charles River Laboratories. [Internet]. Criver.com. Available from: https://bit.ly/3rAaVU1
2. Rapid Microbial Detection | Charles River Laboratories. [Internet]. Criver.com. Available from: https://bit.ly/32qcwDm
3. Rapid Microbial Methods for Short Shelf-Life and ATMP Testing | Charles River Laboratories. [Internet]. Criver.com. Available from: https://bit.ly/3FQ2kRW

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For further information, visit:
www.criver.com/adapt

Introducing the Celsis Adapt™ Concentrator

Finally, a solution for samples with cells.

The Celsis Adapt™ expands the utility of the Celsis® rapid contamination detection platform to cell containing samples for cell culture samples and cellular therapies. Utilizing a proprietary concentration and lysing process, the Celsis Adapt™ and accompanying ATP bioluminescence 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)
- Chimeric antigen receptor-T (CAR-T)
- Chicken Embryo Fibroblast (CEF)
- Mesenchymal Stromal Cells (MSC)
- Human Embryonic Kidney (HEK)

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