Charles River Laboratories Announces Updates to Microbial Solutions Product Portfolio

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New EndoScan-V™ endotoxin detection software and Celsis® automated detection platform for rapid sterility introduced to address unmet industry needs

WILMINGTON, Mass.--(BUSINESS WIRE)--Sep. 9, 2019-- Charles River Laboratories International, Inc. (NYSE: CRL) today announced the launch of two new products in its Microbial Solutions portfolio: an updated EndoScan-V™ software platform for endotoxin detection and measurement; and the introduction of the Celsis® automated detection solution for rapid sterility to ensure continued product quality and contamination control for pharmaceutical manufacturing clients.

EndoScan-V: Enabling Data Driven Decisions

Each year, over 80 million endotoxin detection tests are performed, and endotoxin detection test platforms require software that generates accurate raw data analysis for reporting, tracking and trending of test results.

Charles River's EndoScan-V is a validated endotoxin detection and measurement software used to generate and report quantitative test data. The software performs the requisite measurements, calculations, and creates test reports with the convenience of digital signature report approval. In compliance with regulatory requirements, it generates secure data and audit trails on all actions. The program was designed with flexible capabilities and performance options for gaining operational efficiencies. All aspects of the software form the pillars of data integrity compliance: a fully searchable audit trail, flexible user control and management, and reliable data generation and backup.

When utilized in concert with Charles River's suite of endotoxin detection products, including Charles River Cortex™ software and Endosafe's® bacterial endotoxin testing systems, EndoScan-V supports the secure, automated transfer of generated data, ensuring laboratory and manufacturing processes stay in a state of constant control within a single, end-to-end risk management environment.

Celsis for Sterility: Automated Sterility Results In Just 6 Days

Traditional sterility testing to detect microbial contamination typically requires 14 days of non-value-add incubation. This wait introduces unnecessary risk into the production process in the event of a contamination failure, additional inventory storage requirements, product hold times, and delays to market. Charles River's Celsis rapid sterility test delivers quality control results in just 6 days, allowing manufacturers to quickly confirm the presence or absence of microbial contamination.

The Celsis detection platform for rapid sterility combines Celsis' rapid microbial detection instruments and reagents with innovative partnerships to provide a robust solution for rapid microbial methods (RMM) to optimize the safe release of pharmaceutical and consumer care products. The new platform includes the following enhancements:

- Pre-qualified for background adenosine triphosphate (ATP) consistency, RMM ready consumables from Sartorius, a leading international partner of biopharmaceutical research and the industry.
- Pre-qualified for background ATP consistency, sterility growth media from Hardy Diagnostics, a manufacturer of growth media for microbiological testing in both clinical and industrial laboratories.
- The Celsis Equivalency Validation Report for Rapid Sterility via Membrane Filtration, a commercialized report that demonstrates method equivalency of Celsis rapid microbiology to the compendial membrane filtration-based sterility test. The contents of this report represent significant cost and time savings laboratories would otherwise spend validating an alternative rapid test method, allowing them to immediately begin addressing other validation criteria.

These new product offerings complement the currently available Celsis rapid microbial detection automated instruments and reagents, which deliver definitive results and data integrity, including:

- Celsis AMPiScreen®, a proprietary reagent kit that can confirm the presence of ultra-low levels of microbiological contamination >50% faster than the compendial sterility test.
- Celsis AMPiScreen reagents include everything needed for rapid microbial detection and eliminate the inherent subjectivity of traditional sterility test by providing a definitive positive or negative result.
- The Celsis Advance II™ system designed for high throughput manufacturers, and capable of running 120 assays per hour.
- The Celsis Accel® system, intended for small and mid-sized pharmaceutical, home, and beauty product manufacturing facilities, capable of running 30 assays per hour.

Approved Quotes

- "Our Microbial Solutions team believes in continuous improvement and innovation. We are constantly taking the pulse of our industries, and are proud to provide industry-leading solutions to common problems." – Foster T. Jordan, Corporate Senior Vice President, Microbial Solutions, Charles River
- "We believe in the power of data. EndoScan-V meets the highest standards of data integrity, and provides users

confidence in the quality and safety of their endotoxin detection data.” – Nicola Reid, Associate Director, Microbial Solutions Product Management, Charles River

- “The Celsis automated detection platform for rapid sterility is unlike anything else available in the industry. While maintaining the established sample prep aspects of the traditional test, the technology delivers definitive sterility results in 6 days, less than half the time of the compendial test allowing manufacturers to release critical therapies to patients faster and more safely.” – Julie Sperry, Senior Director, Microbial Solutions Product Management & Strategic Marketing, Charles River

About Charles River

Charles River provides essential products and services to help pharmaceutical and biotechnology companies, government agencies and leading academic institutions around the globe accelerate their research and drug development efforts. Our dedicated employees are focused on providing clients with exactly what they need to improve and expedite the discovery, early-stage development and safe manufacture of new therapies for the patients who need them. To learn more about our unique portfolio and breadth of services, visit www.criver.com.

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