

# Rapid Micro Biosystems Announces the Commercial Availability of the Growth Direct(TM) System for Sterility Testing

New Application Significantly Reduces Time-to Result of Traditional Sterility Test

LOWELL, Mass., Oct. 19, 2015 (GLOBE NEWSWIRE) -- Rapid Micro Biosystems, the provider of automated, rapid, non-destructive detection and enumeration technologies in microbiology, today announced the launch of the sterility testing application for the Growth Direct™ System. The Growth Direct System automates the incubation, detection, and reporting steps for pharmaceutical quality control laboratories. The sterility test mirrors the compendial method sterility test, supporting both aerobic and anaerobic test conditions. Sterility testing joins the other application supported by the Growth Direct System, including environmental monitoring and bioburden testing. The technology is based on the detection of the natural auto-fluorescence of microorganisms, and can detect growing colonies in about half the time of the traditional 14-day sterility test, providing a significant time savings.

Developed in part with funds from the Biomedical Advanced Research and Development Authority (BARDA) as part of BARDA's Science and Technology Platforms Applied to Medical Countermeasure (MCM) Development program, the Growth Direct System for Sterility Testing revolutionizes pharmaceutical microbial quality control testing while adhering to the stringent regulatory requirements of the sterility test.

"BARDA has been a strong partner in the development of this technology," said Julie Sperry, Vice President of Marketing, Product Management and Services at Rapid Micro Biosystems. "Having the support of the Department of Health and Human Services indicates how critical a rapid sterility test is to both manufacturers and the regulatory community."

The technology supports testing of filterable samples and is designed for high and low volume sterility testing environments.

- **Positive Results Starting in Hours:** The test provides early detection of a positive microbial contamination allowing faster response to contamination events.
- **7 Days Versus 14:** Final results of the sterility test are available in half the time of the traditional test.
- **Discrete Colonies:** Growth occurs on the surface of a membrane and colonies can be "picked" directly, eliminating the time and labor necessary with a subculture step

- **Closed Loop:** Sample preparation is closed looped and performed in an isolator or in a clean room, similar to the existing method. The test replicates both anaerobic and aerobic test conditions.
- **Non-Destructive:** No additional reagents are added. Samples with positive results can continue to grow.
- **Complete Audit Trail:** A complete history of user activity as well as sample processing are available, ensuring compliance with 21 CFR Part 11.

“Saving manufacturers 7 days of sterility testing time delivers a significant financial benefit by accelerating product manufacturing and final product release,” states Wendy Hinchey, Vice President of Sales. “Demand for the solution to this time consuming test has been very strong, as companies realize the resulting value the system provides their organizations.”

“The release of our sterility application represents a significant milestone in Rapid Micro Biosystems’ goal to automate key microbial tests in the manufacturing quality control lab,” said Robert Spignesi, President and CEO of Rapid Micro Biosystems. “Our rapid sterility application, along with our environmental monitoring and bioburden applications, offers quality control labs options to improve productivity and streamline testing while closely aligning to traditional methods.”

### **About Rapid Micro Biosystems**

Rapid Micro Biosystems delivers the Growth Direct System, an automated, non-destructive rapid detection and enumeration technology based on the compendial method for microbial quality control in pharmaceutical manufacturing. The system automates and accelerates detection and enumeration in the areas of sterility testing, environmental monitoring, and bioburden testing, eliminating manual steps and analysis. The detection technology, first developed and patented by Dr. Don Straus, Ph.D., uses the natural auto-fluorescence of microbes and requires no reagents. This work was supported by the Biomedical Advanced Research and Development Authority Contract Number HHSO100201000056C. For more information about Rapid Micro Biosystems visit [www.rapidmicrobio.com](http://www.rapidmicrobio.com).

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