

Sterility Testing

A new application leveraging the Growth Direct™ technology

The Growth Direct™ System for Sterility revolutionizes pharmaceutical microbial quality control testing while adhering to the stringent regulatory requirements of sterility testing. The technology supports testing of filterable samples for anaerobic and aerobic testing, and is designed for high and low volume sterility testing environments.

7 Days Versus 14

The Growth Direct™ for Sterility cuts testing time in half. Final results of sterility testing are available in half the time of the current test.

Positive Results in Hours

The device provides early detection of a positive microbial contamination allowing faster response to contamination events.

Closed Loop

Sample preparation is closed looped and performed in an isolator or in a clean room, similar to the existing method. The test includes both anaerobic and aerobic test cassettes.

Non-Destructive

No additional reagents are added. Samples with positive results can continue to grow for additional analysis of the micro organism colony through a microbial identification system.



Available in 2013

Frequently Asked Questions

What types of contaminants are detected?

The Growth Direct™ System for Sterility detects molds, yeasts, aerobic and anaerobic bacteria

Will my sample preparation have to change?

In most cases sample preparation will be the same as your current processes.

Would this be validated as an alternative method?

The method is considered an alternative for sterility testing; however, it aligns with other validated alternative sterility methods. Rapid Micro Biosystems' validation team is available to streamline the validation process.

What type of growth media is used?

The system uses a blood-based media for growth.

What is the expected throughput?

The device will process 20 sterility samples per day.

How large is the new device?

The device is comparable in size to a floor standing incubator or a -80°C freezer. The approximate measurements are 55" (140 cm) wide by 37" (94 cm) deep. The height of the device is 94" (239 cm).



How are consumables packaged?

The Growth Direct™ consumables are packaged for use in a clean room or isolator.

What kind of services and support are available?

Rapid Micro Biosystems provides multiple levels of support from installation and validation, application, preventative maintenance and service. We ensure the consistent and high efficiency operation of the Growth Direct™ System.



What is the cost of the Growth Direct™ System for Sterility Testing?

The device is priced to ensure a compelling return on investment for the micro quality control lab. Speak with a Rapid Micro Biosystems representative who will provide a quotation and help you build your case.

Where can I see the device?

Rapid Micro Biosystems will host events in Bedford, MA, featuring the device. Visit www.rapidmicrobio.com/workshops to register for one of these events.