

Custom Microbial Studies

WuXi AppTec's Atlanta facility has a laboratory dedicated to performing custom microbial studies. With our many years of experience in conducting microbiology/microbial testing, we also offer clients extensive expertise in developing custom protocols to meet specific needs.

Standard methods (ASTM, AOAC, USP, ISO, etc.) can be modified, expanded or otherwise customized to provide specialized challenges or fulfill particular requirements.

WuXi AppTec is a global leader in providing discovery, testing and manufacturing services for the pharmaceutical, biologics and medical device industries. Research-driven and customer-focused, with operations in China and the U.S., WuXi AppTec offers a broad and integrated portfolio of services designed to assist our customers with cost-effective and efficient outsourcing solutions.

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Commonly requested categories of customized tests include:

Surface Cleaning Validation / Efficacy of Sanitizers

This type of study is used to determine the efficacy of sanitizing agents on various inanimate surfaces, such as counters, floors, and other areas/materials that are routinely cleaned. It is typically conducted with variety of microorganisms, most often those that are of concern in the environment or in product application.

ASTM E1153 is the method commonly used to run this type of study. The experiment will also include a validation of the neutralizer solution (e.g., per ASTM E1054) to ensure that the results of the challenge experiments are not adversely influenced by carry-over of the sanitizer solution.

Disinfection Efficacy

This type of study is used to evaluate the log reduction of challenge organisms when exposed to specific disinfection agents or antimicrobial processes. It is typically conducted with a variety of microorganisms – a panel of organisms typically used for efficacy testing; those organisms that are of the most concern to product integrity or application; or environmental/product isolates.

Areas of particular application include demonstration of the percent or log reduction related to disinfection steps used in tissue processing, as well as medical product disinfection at point of use (where sterilization is not possible or feasible). Studies may be customized based on AOAC, ASTM and other compendial methods.

Microbial Ingress / Microbial Barrier Challenge

This type of study is used to evaluate the effectiveness of various barriers or product-specific procedures in blocking the physical passage of microorganisms. The study is typically conducted with clinically or environmentally relevant isolates or those that would pose the greatest challenge to the barrier.

Contact a WuXi AppTec Account Manager to learn more about our comprehensive menu of microbial studies and the many available customizing options.

**For more information on
WuXi AppTec's services
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