

Antimicrobial Testing for Medical Devices and Industrial Products

WuXi AppTec offers the following assays to determine the antimicrobial activity of medical devices, components or other materials treated with antimicrobial agents.

USP <51>, Antimicrobial Effectiveness Test

Used to determine the effectiveness of antimicrobial substance(s) in injections, parenteral emulsions, otic, nasal and ophthalmic products. May also be used for topical and oral products or those in a liquid, gel or semi-solid state. Typically conducted with a panel of three (3) bacteria and two (2) fungi.

USP <1227>, Neutralization Validation

Used to evaluate the method chosen to neutralize the antimicrobial properties of a product prior to estimating the number of viable microorganisms. It is done to ensure the validity of the test results achieved during the USP Antimicrobial Effectiveness Test and other microbial recovery tests.

ASTM E-1153

Used to determine the efficacy of sanitizing agents on various inanimate surfaces, such as counters, floors 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 E-2149 (Dow 0923, Shake Flask)

Used to quantitatively evaluate the effectiveness of a sample treated with a non-leaching antimicrobial by shaking in an organism suspension. The typical challenge organism is *Klebsiella pneumoniae*.

ASTM E-2180

Used to quantitatively evaluate the effectiveness of an antimicrobial agent incorporated into hydrophobic polymeric material. Recommended challenge organisms are *Staphylococcus aureus* and *Pseudomonas aeruginosa* (or *Klebsiella pneumoniae*).

ASTM G-21

Used to qualitatively evaluate the ability of the synthetic polymeric test material to support the growth of a mixture of five (5) fungi. The synthetic polymeric test material is usually provided in the form of molded and fabricated articles, tubes, rods, sheets and film materials.

AATCC Method 30, Part III

Used to qualitatively evaluate antifungal activity of a textile sample when challenged with *Aspergillus niger*.

AATCC Method 100

Used to quantitatively evaluate the antimicrobial effectiveness of a textile product when challenged with *Staphylococcus aureus* and *Klebsiella pneumoniae*.

AATCC Method 147

Used to qualitatively evaluate the antimicrobial activity of diffusible antimicrobial treatments on textile products when challenged with *Staphylococcus aureus* and *Klebsiella pneumoniae*.

AATCC Method 174 Part 1

Used to qualitatively evaluate the antimicrobial activity of carpet when challenged with *Staphylococcus aureus* and *Klebsiella pneumoniae*.

AATCC Method 174 Part 2

Used to quantitatively evaluate the antimicrobial effectiveness of carpet when challenged with *Staphylococcus aureus* and *Klebsiella pneumoniae*.

AATCC Method 174 Part 3

Used to qualitatively evaluate the antifungal activity of carpet when challenged with *Aspergillus niger*.

Zone of Inhibition / Kirby-Bauer

Used to demonstrate activity/potency of antimicrobials or antibiotics, based on measuring the zone of inhibition observed for specified microorganisms. Areas of particular application include materials treated or infused with an antimicrobial agent that leaches out of the material.

Any of the standard test methods listed here can be modified to include different/additional organisms as well as different/additional exposure times.

CUSTOM ANTIMICROBIAL STUDIES

With years of experience conducting microbiology/microbial testing and a laboratory dedicated to performing custom microbial studies, WuXi AppTec offers clients extensive expertise in developing custom protocols to meet specific needs.

Custom studies can be designed for:

- Drug or biological substances
- Medical devices
- Preservatives
- Textiles
- Tissue (human and animal)
- Variety of bacteria, yeast and filamentous fungi

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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