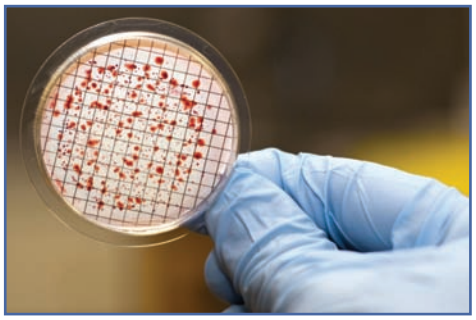
antimicrobial *in-vitro* testing for medical devices



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

With years of experience conducting microbiology/microbial testing, we also provide clients with extensive expertise in developing custom protocols to meet specific needs.

USP <51>, Antimicrobial Effectiveness Test
Determines the effectiveness of antimicrobial (preservative) substances for the following products: injections and other parenterals including emulsions, otic products, sterile nasal products and ophthalmic products made with aqueous bases or vehicles; topically used products made with aqueous bases or vehicles, non-sterile nasal products, and emulsions, including those applied to mucous membranes; oral products other than antacids, made with aqueous bases or vehicles; antacids made with an aqueous base.

USP <1227>, Neutralization Validation
Validates the method chosen to neutralize the antimicrobial properties of any product with inhibitory or microbicidal activity. (Accurate determination of efficacy requires effective inactivation or neutralization of the antimicrobial agent.) Typically performed prior to conducting USP Antimicrobial Effectiveness testing and other microbial recovery tests.

ISO 22196 / JIS Z 2801
Quantitatively evaluates the activity and efficacy of anti-microbials on the surface of antibacterial and antimicrobial products, including intermediate products.

Zone of Inhibition
Determines the activity of antimicrobials or antibiotics by the presence or absence of a zone of inhibition surrounding the test material, which is measured for specified microorganisms. Applications include materials treated or infused with an antimicrobial agent that leaches out of the material.

ASTM E-1153, Sanitizer Efficacy
Determines the efficacy of sanitizing agents on various inanimate surfaces, such as counters, floors and other areas/materials that are routinely cleaned. Typically conducted to validate sanitizing procedures for cleanrooms or aseptic processing areas.

ASTM E-2149, Dynamic Contact
Evaluates the resistance of antimicrobial-treated devices by exposing the test sample to known concentrations of micro-organisms under dynamic conditions.

ASTM E-2315, Time-Kill Procedure
Quantitatively evaluates the changes of a population of micro-organisms within a specified sampling time when exposed to a test material or a dilution of the test material. Time points may be selected based on intended use of the material or over a longer period of time to develop a kill model for the material. Challenge organisms may be standardized strains or representative of microorganisms encountered under test material use.

ASTM E-2180
Evaluates the effectiveness of incorporated or bound antimicrobial agents in hydrophobic polymeric materials, including plastics, epoxy resins, and other hard surfaces.

IN-VIVO STUDIES
Specially designed assays are also available using animal models to assess antimicrobial efficacy of devices. Contact your WuXi AppTec Account Manager for more information.

Talk to us and find out how our antimicrobial testing services can work for you.

Contact a WuXi AppTec Account Manager at 651-675-2000 or email: info@wuxiapptec.com

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