

Antimicrobial Efficacy Studies



HOW TO

**Discover a way to differentiate
your product from the competition**

WuXi AppTec

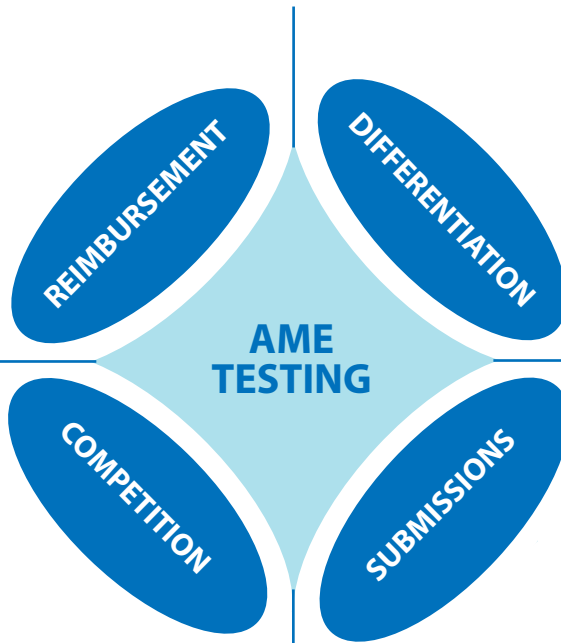
The Leader in Combination Product Services



Why do antimicrobial efficacy (AME) testing?

Four major considerations are driving the focus on antimicrobial efficacy testing.

Hospitals and physicians are preferentially using medical devices proven to reduce risk of hospital-acquired infections because many HAs are not reimbursed.



Products are being evaluated and selected based on the strength of their demonstrated antimicrobial properties.

When evaluating products – whether competing or stand-alone – physicians recognize the value of quantitative data that has been generated in a biologic system.

Scientifically valid and clinically relevant data is needed to support antimicrobial efficacy claims.

Why do your AME testing with WuXi AppTec?

We are the clear leader in this field with exceptional expertise.

EXPERIENCED

WuXi AppTec successfully developed and established its first FDA-approved in-vivo infection model in 2005.

KNOWLEDGEABLE

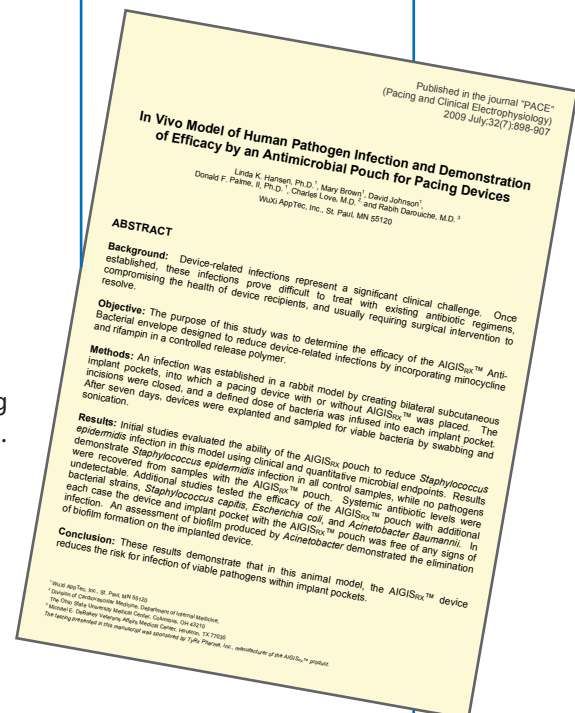
Our AME program is continually expanding to support a variety of clinically relevant models and validate a growing number of microbial strains.

PEER-REVIEWED

A peer-reviewed article in 2009 reported on our in-vivo quantitative data, which was used in securing approval of an AME claim without using clinical data.

RECOGNIZED

Over 1/3 of the top medical device companies have completed AME studies with us.



Differentiate your product with clinically relevant data

WuXi AppTec's established and robust methodologies provide you with clinically relevant data to support your R&D, regulatory and marketing needs.

Determining and quantitatively measuring the efficacy of an antimicrobial agent is complex and includes the testing of non-biofilm (planktonic) bacteria, biofilm and biologic response. Our comprehensive three-tier antimicrobial efficacy testing program is one of the first to provide relevant *in-vitro* and FDA-accepted *in-vivo* data to speed formulation selection, verify product performance, and confirm the efficacy of antimicrobial agents when combined with devices.

TIER 1

Screening / In-Vitro Testing



Quickly evaluate activity and potency of antimicrobial agents.

- High-volume screening of antimicrobial formulations and doses.
- Validated USP, ASTM, JIS, ISO and AATCC standards.
- Qualitative and quantitative evaluations that include Zone of Inhibition, Log Reduction and Time-Kill studies.

TIER 2

In-Vitro Biofilm Quantification



Evaluate candidate materials and dose levels to determine impact on biofilm formation.

- Evaluation of a broad selection of antimicrobial formulations and dosing candidates.
- Comparison of biofilm levels for treated-product coupons following established ASTM methodologies.
- Quantitative data on biofilm formation, free from interference of host infection response.

TIER 3

In-Vivo Studies



Evaluate antimicrobial effectiveness of final product candidates in a biologic system.

- Numerous validated bacterial strains and customized testing models available for your unique therapeutic application.
- Established protocols and submission-ready results for label claims.
- Clinically relevant data validating the antimicrobial efficacy of your device candidates vs. controls or competitive products.

Antimicrobial Efficacy (AME) Studies

AME EXPERIENCE

WuXi AppTec is the clear leader in this field with exceptional expertise and experience.

Since the inception of our AME program, we have:

- ▶ Developed protocols utilized in FDA-accepted studies.
- ▶ Validated numerous bacterial strains – including clinical isolates – for *in-vivo* studies.
- ▶ Performed over 100 *in-vivo* AME studies and averaged over 300 *in-vitro* samples tested per month.

PROGRAM FEATURES

- ▶ Testing is custom designed with sponsor for each test article.
- ▶ Infection models are developed for specific device applications.
- ▶ In-house bank of nearly 200 bacterial strains, including ATCC stocks and clinical isolates.
- ▶ Regulatory and consulting services available to support sponsors.



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Contact WuXi AppTec for your next Antimicrobial Efficacy study:

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