



AATCC TEST METHOD 100 FOR ASSESSING THE ANTIMICROBIAL PROPERTIES OF WOUND DRESSINGS

Solid antimicrobial dressings are a standard in the wound care market. Dressings are available in many forms including woven and non-woven textiles, polymer foams, and swelling and/or absorbent materials. The American Association of Textile Chemists and Colorists (AATCC) professional association lists Test Method 100 as a suitable technique for assessing the effects of antimicrobial finishes on textile materials. This method has become the industry standard for evaluating antimicrobial fabrics and is also recognized by the US Food and Drug Administration (FDA) as a standard technique for establishing antimicrobial activity within wound dressings for 510(k) filings.

WHAT IS IT?

Test Method 100 evaluates the effectiveness of antimicrobial finishes on textile materials. The test articles are directly inoculated with the test organism and incubated at variable times depending on the application (typically at least 24 hours). The test articles are then placed in neutralizing solution and the microbes are recovered and enumerated.

WHY USE IT?

Test Method 100 is the industry standard for evaluating the antimicrobial efficacy of textiles. It provides a quantitative assessment of growth inhibition or microbial killing within the wound dressing material. The results can be used for 510(k) filings or other product claims for marketing purposes.

IMPORTANT CONSIDERATIONS FOR DESIGNING AATCC TEST METHOD 100 STUDIES

If possible, dressings should be tested by simulating the intended use of the product. This also includes defining a "worst-case" scenario for the specific product that takes into account the length of time the product comes in contact with the wound and the type of the wounds it will be used for, i.e., low or high exudate wounds.

Form of Dressing: Test Method 100 is typically used to support antimicrobial claims for solid dressings. Different dressing materials, such as foams, non-woven and woven fabrics, superabsorbent fibers, and wicking fabrics, all present unique challenges when developing robust test protocols. The dressing form factor and intended use will define how other important test variables should be considered.

Absorption Capacity: The amount of test medium is an important consideration and can greatly impact the antimicrobial effect of a given dressing as well as the reliability of the assay results.

Test Medium: Historically, many 510(k)-cleared wound dressings report antimicrobial data from Test Method 100 using buffer with physiological salts (e.g., PBS or similar) as the test medium; however, if the dressing contacts the wound bed, it is advisable to also consider using simulated wound fluid (contains serum, peptone, and physiological salts) as a more relevant challenge medium.



Test Organism: The Test Method 100 protocol calls for evaluation using one gram-positive and one gram-negative bacteria, *Staphylococcus aureus* and *Klebsiella pneumoniae*, respectively. However, to support antimicrobial claims, the FDA recommends testing against at least one gram-positive and one gram-negative bacteria, one yeast, and one mold. Below are standard lab strains available from the American Type Culture Collection (ATCC) iFyber routinely uses in these studies (other species and strains available upon request):

TARGET CATEGORY	SPECIES	ATCC NUMBER
Gram-negative	<i>Pseudomonas aeruginosa</i>	15442
Gram-positive	<i>Staphylococcus aureus</i>	6538
Yeast	<i>Candida albicans</i>	10231
Mold	<i>Aspergillus brasiliensis</i>	16404

Test Article Neutralization: Prior to initiation of Test Method 100 studies, it is important to perform an assessment of test article neutralization in order to identify the proper parameters for neutralization of the actives so that the antimicrobial activity can be accurately calculated.

iFyber is a preclinical research organization offering customized services to companies that operate at the interface of chemistry, microbiology, and materials science. iFyber is unique. We pride ourselves on providing access to top scientists and creatively solving problems with quick turnaround times.

THINK OF IFYBER AS:

- Consultants with a laboratory to back up ideas with data
- An academic lab, solving R&D problems on corporate or start-up timelines
- A testing lab that develops new methods tailored to clients' products and services
- An extension of your quality, regulatory, and R&D teams