



Designation: E 2197 – 02

Standard Quantitative Disk Carrier Test Method for Determining the Bactericidal, Virucidal, Fungicidal, Mycobactericidal and Sporocidal Activities of Liquid Chemical Germicides¹

This standard is issued under the fixed designation E 2197; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

INTRODUCTION

The quantitative test method described here uses disks of stainless steel (1 cm in diameter) as carriers. Because it employs the same basic set of materials and procedures to assess the ability of liquid chemical germicides to inactivate vegetative bacteria, viruses, fungi, mycobacteria and bacterial spores **(1,2)**² it unifies the test methodology against a wide array of microorganisms. Performance standards for the categories of products to be tested, and the specific types of organism(s) to be used may vary depending on the regulatory agency. This basic test can also be adapted for use with other carrier materials of similar dimensions.

The development of this method was made possible with financial support from the Antimicrobials Division of the U.S. Environmental Protection Agency.

1. Scope

1.1 The method is designed to evaluate the ability of liquid chemical germicides to inactivate vegetative bacteria, viruses, fungi, mycobacteria and bacterial spores in the presence of a soil load **(1,2)** on disk carriers that represent environmental surfaces and medical devices. It is also designed to have survivors that can be compared to mean of no less than three control carriers to determine if the performance standard has been met. For proper statistical evaluation of the results, the size of the test inoculum should be sufficiently large to take into account both the performance standard and the experimental variation in the results.

1.2 The test protocol does not include any wiping or rubbing action. It is, therefore, not designed for testing germicide-soaked wipes.

1.3 This test method should be performed by persons with training in microbiology in facilities designed and equipped for work with infectious agents at the appropriate biosafety level **(3)**.

1.4 In this test method, metric units are used for all applications, except for distance in which case inches are used and metric units follow.

1.5 It is the responsibility of the investigator to determine whether Good Laboratory Practice Regulations (GLPs) are

required and to follow them where appropriate (40 CFR, Part 160 for EPA submissions and 21 CFR, Part 58 for FDA submissions).

1.6 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 ASTM Standards:

D 1129 Terminology Relating to Water³

D 1193 Specification for Reagent Grade Water³

E 1054 Practices for Evaluating Inactivators of Antimicrobial Agents Used in Disinfectant, Sanitizer, Antiseptic, or Preserved Products³

E 2111 Standard Quantitative Carrier Test Method to Evaluate the Bactericidal, Fungicidal, Mycobactericidal and Sporocidal Potencies of Liquid Chemical Germicides⁴

2.2 CFR Standard:

40 CFR, Part 160; 21 CFR, Part 58⁵

2.3 Other Documents:

Disinfectants (Chapter 6), Official Methods of Analyses (1998)⁶

¹ This test method is under the jurisdiction of ASTM Committee E35 on Pesticides and is the direct responsibility of Subcommittee E35.15 on Antimicrobial Agents.

Current edition approved April 10, 2002. Published June 2002.

² The boldface numbers in parenthesis refer to the list of references at the end of this standard.

³ Annual Book of ASTM Standards, Vol 11.01. and 11.05

⁴ Annual Book of ASTM Standards, Vol 11.05

⁵ Available from Superintendent of Documents, U.S. Government Printing Office, Washington D.C. 20402.

⁶ Available from AOAC International, Washington, DC.