



Standard Quantitative Carrier Test Method To Evaluate the Bactericidal, Fungicidal, Mycobactericidal and Sporocidal Potencies of Liquid Chemical Germicides¹

This standard is issued under the fixed designation E 2111; 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 need for better tests to assess the germicidal activity of chemicals has been recognized **(1)**² and several investigations conducted in the past decade have been aimed at developing simpler and fully quantitative tests while attempting to design protocols suitable for working with a wide variety of microorganisms **(2)**. The method described here uses glass vials as carriers and the same basic set of materials and procedures can be used to test the potency of liquid chemical germicides against vegetative bacteria, fungi, mycobacteria and bacterial spores. It is not appropriate, however, for working with viruses because of the relatively high levels of eluate dilutions required and the need for membrane filtration. Further evaluation of products under more stringent test conditions may be necessary for their registration. Performance standards for the categories of products to be tested and the specific types of organism(s) to be used may also vary depending on the regulatory agency.

1. Scope

1.1 This test method is designed for use in product development and for the generation of product potency data. The loading of each carrier with a known volume of the test organism suspension is possible. The incorporation of control carriers also allows for an assessment of the load of viable test organism on the test carriers.

1.2 This test method is designed to have survivors and also to be used with a performance standard. The surviving microorganisms on each test carrier are compared to the mean of no less than three control carriers to determine if the performance standard has been met. To allow proper statistical evaluation of 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. For example, if an arbitrary performance standard of 6-log₁₀ reduction in the viability titer of the test organism is used, and an inoculum size of 10⁷ CFU, then theoretically a maximum of ten survivors per carrier is permitted; however, because of experimental variability the exact target may need to be higher than 10⁶ CFU/carrier, thus fewer survivors would be permitted.

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

1.4 *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.*

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

1.6 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).

2. Referenced Documents

2.1 ASTM Standards:

D 1129 Terminology Relating to Water³

D 1193 Specification for Reagent Grade Water³

E 1054³ Practices for Evaluating Inactivators of Antimicrobial Agents Used in Disinfectant, Sanitizer, Antiseptic, or Preserved Products³

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

Current edition approved Oct. 10, 2000. Published March 2001.

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

³ *Annual Book of ASTM Standards*, Vol 11.01.