



Standard Quantitative Carrier Test Method to Evaluate the Bactericidal, Fungicidal, Mycobactericidal, and Sporocidal Potencies of Liquid Chemicals¹

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INTRODUCTION

The need for better tests to assess the microbicidal activity of chemicals was recognized **(1)**² and several simpler and quantitative test methods have been developed for working with a wide variety of microorganisms **(2)**. The test method described here uses glass vials as carriers; the same basic set of materials and procedures can be used to test the potency of liquid microbicides against vegetative bacteria, fungi, mycobacteria, and bacterial spores. However, the test method is not appropriate for use 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. This test method permits the loading of each carrier with a known volume of the test organism. The incorporation of controls can also determine the initial load of colony forming units (CFU) of organisms on the test carriers and any loss in CFU after the mandatory drying of the inoculum.

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 In this test method, SI units are used for all applications, except for distance, in which case inches are used and SI 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*:³

D1129 Terminology Relating to Water

D1193 Specification for Reagent Water

E1054 Test Methods for Evaluation of Inactivators of Antimicrobial Agents

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

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

³ For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.