



Standard Test Methods for Evaluation of Inactivators of Antimicrobial Agents¹

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1. Scope

1.1 These test methods are used to determine the effectiveness of procedures and agents for inactivating (neutralizing, quenching) the microbicidal properties of antimicrobial agents, and to ensure that no components of the neutralizing procedures and agents, themselves, exert an inhibitory effect on microorganisms targeted for recovery.

NOTE 1—Knowledge of microbiological and statistical techniques is required for these procedures. These methods are not suitable when testing the virucidal activity of microbicides (see Test Method E1482).

1.2 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.3 *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:²

E645 Test Method for Efficacy of Microbicides Used in Cooling Water Systems

E1115 Test Method for Evaluation of Surgical Hand Scrub Formulations

E1482 Practice for Use of Gel Filtration Columns for Cytotoxicity Reduction and Neutralization

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *antimicrobial, adj*—describes an agent that kills or inactivates microorganisms or suppresses their growth or reproduction.

3.1.2 *antimicrobial effectiveness evaluation, adj/n*—a determination of microbicidal properties of an antimicrobial agent by methods, such as Test Methods E645 and E1115.

3.1.3 *CFU/mL (abbrev.)*—colony-forming units of a microorganism per millilitre of fluid.

3.1.4 *neutralization, n*—a physical or chemical procedure that inactivates or quenches the microbicidal properties of an antimicrobial agent.

3.1.5 *neutralizer effectiveness, adj/n*—ability of a neutralization procedure to inactivate or quench the microbicidal properties of an antimicrobial agent.

3.1.6 *neutralizer toxicity, adj/n*—any inhibitory effects a neutralization procedure may have on the survival of a microbial population.

3.1.7 *test material control, adj/n*—an evaluation of the activity of a test material in reducing a known population of microorganisms.

3.1.8 *test organism viability, adj/n*—the population of a challenge microorganism used in a neutralization assay.

3.1.9 *viability, n*—the ability of a challenge microorganism to form colonies or grow on a nutrient medium.

3.1.9.1 *Discussion*—In the context of these test methods, “viability” is understood to be synonymous with culturability.

4. Summary of Test Methods

NOTE 2—The neutralization test method selected must be consistent with the methods of testing used in the antimicrobial effectiveness evaluation.

4.1 *Neutralization Assay with Recovery on Semi-solid Medium*—Neutralization assay for antimicrobial effectiveness tests that recover and quantify microbial populations on solid (agar) media. This method is appropriate for antimicrobial agents that are chemically inactivated or diluted to sub-inhibitory levels and performed entirely *in vitro* or including an *in vivo* component to verify neutralization of an antimicrobial formulation sampled from the skin of a human volunteer.

4.2 *Neutralization Assay with Recovery in Liquid Medium*—Neutralization assay for antimicrobial effectiveness tests that recover surviving microbial populations in liquid media for a growth/no growth determination. This method is appropriate for antimicrobial agents that are chemically inactivated or diluted to sub-inhibitory levels.

¹ These test methods are under the jurisdiction of ASTM Committee E35 on Pesticides, Antimicrobials, and Alternative Control Agents and are the direct responsibility of Subcommittee E35.15 on Antimicrobial Agents.

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² 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.