Designation: E 1052 – 96

Standard Test Method for Efficacy of Antimicrobial Agents Against Viruses in Suspension[1]

This standard is issued under the fixed designation E 1052; 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.

1. Scope

1.1 This laboratory test method is a suspension test used to evaluate the effectiveness of antimicrobial solutions against specific viruses. This test method may be employed with most viruses and is designed for cell culture host systems.

1.2 This test method should be performed only by those trained in microbiological or virological techniques.

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.* The user should consult a reference for the laboratory safety recommendations.[2]

1.4 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 andCFR, Part 58 for FDA submissions). Refer to the appropriate regulatory agency for performance standards of virucidal efficacy.

2. Referenced Documents

2.1 *ASTM Standards:*

E 1053 Test Method for Efficacy of Virucidal Agents Intended for Inanimate Environmental Surfaces[3]

E 1153 Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces[3]

E 1482 Test Method for Neutralization of Virucidal Agents in Virucidal Efficacy Evaluation[3]

2.2 *Federal Standards:*[4]

Title 40, Code of Federal Regulations (CFR), Environmental Protection Agency, Part 160, Good Laboratory Practice Standard

Title 21, Code of Federal Regulations (CFR), Food and Drug Administration, Part 58, Laboratory Practice for Nonclinical Laboratory Studies

3. Summary of Test Method

3.1 One part of the virus suspension is added to nine parts of the appropriately diluted antimicrobial. The virus is exposed to the virucide for the length of time that is representative of actual use conditions or the label directions of the product (for example, from 15 sec for a handsoap to 10 min or longer for a antimicrobial solution). The tests also should be performed at the temperature most representative of actual use conditions (usually 22 ± 2°C). The virus-antimicrobial mixture is assayed in a host system appropriate for the test virus. The virus titer of the stock virus is determined by the median cell culture infective dose ($CCID_{50}$), plaque assay or other quantifiable measure of infectivity. Cytotoxicity to the host system (from the antimicrobial) at the tested concentration also is determined. The virus-antimicrobial mixture is assayed in numerous units of the host system at a dilution just beyond the cytotoxic range of the antimicrobial. At least three replicate determinations are performed on controls and experimentals to confirm virus inactivation by a batch of antimicrobial. Results are recorded as the median value of $\log_{10}$-virus inactivation.

3.2 This test method is designed to be performed by a trained microbiologist or virologist who is responsible for choosing the appropriate host system for the test virus, and applying the techniques necessary for propagation and maintenance of host and test virus. For a reference text, refer to Schmidt and Emmons.[5]

4. Significance and Use

4.1 This test method is to be used to determine the effectiveness of antimicrobial solutions against designated prototype viruses that are in suspension.

4.2 The effective antimicrobial concentration should be determined using cell cultures as the host system for specific viruses.

4.3 This suspension test is for special applications of virucides, such as inactivation of viruses in contaminated liquid wastes, and as a first stage in determining virucidal potential of

[1] This test method is under the jurisdiction of ASTM Committee E-35 on Pesticides and is the direct responsibility of Subcommittee E35.15 on Antimicrobial Agents.

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[2] CDC-NIH, *Biosafety in Microbiological and Biomedical Laboratories*, Third Edition, U.S. Department of Health and Human Services, Washington, DC, May 1993.

[3] *Annual Book of ASTM Standards*, Vol 11.05.

[4] Available from U.S. Government Printing Office, Superintendent of Documents, Washington, DC 20402.

[5] *Diagnostic Procedures for Viral, Rickettsial and Chlamydial Infections*, N. J. Schmidt and W. W. Emmons, Eds, Sixth Edition, Amer. Pub. Hlth. Assoc., Washington, DC 1989.