Designation: E2756 – 10

Standard Terminology Relating to Antimicrobial and Antiviral Agents[1]

This standard is issued under the fixed designation E2756; 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 The purpose of this terminology standard is to establish uniformity in terms used in the field of antimicrobial and antiviral agent testing. Terms are adapted from related fields such as regulatory terms defined by law and definitions as supported by test requirements.

1.2 The terms are appropriate to the wide range of interest related to standards developed in the area of antimicrobial and antiviral testing.

2. Terminology

GENERAL ANTIMICROBIAL AND ANTIVIRAL TERMS

accuracy, *n*—a measure of the degree of conformity of a value generated by a specific procedure to the assumed or accepted true value, and includes both precision and bias.

ambient temperature, *n*—temperature of the environment in which a test method is performed.

antibacterial, *adj*—describes an agent that kills bacteria or suppresses their growth or reproduction.

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

antiseptic, *n*—a material for use on living tissue that either destroys microorganisms or suppresses their growth.

bias, *n*—a systematic error that contributes to the difference between the mean of a large number of test results and an accepted reference value (ASTM Form and Style Manual).

DISCUSSION—A statement of bias is not possible because standard reference materials are not available for most microbiological methods.

biofouling, *n*—the unwanted accumulation of organisms and/or their products on surfaces.

cleaner-sanitizer, *n*—a physical or chemical agent that removes soil from an object and reduces numbers of microorganisms on non-food contact surfaces.

carrier, *n*—a surrogate surface or matrix that facilitates the interaction of test microorganisms and treatment(s).

cell monolayer, *n*—a single layer of eukaryotic cells typically propogated on a glass or plastic surface to which they are securely attached.

cleansing wash, *n*—a procedure intended to remove soil or residue.

clastogen, *n*—an agent that reduces chromosomal breakage.

composite sample, *n*—a series of grab samples integrated into a single sample or samples collected at specific times and integrated into a single sample.

cooling system, *n*—equipment and coolant used for the removal of heat from processes, equipment, or both.

cooling water, *n*—any water-based solution that absorbs and transfers heat in cooling systems.

cumulative effect, *n*—a progressively additive reduction in the numbers of viable microorganisms measured from an established baseline following repeated applications of a material or procedure.

decontamination, *n*—a procedure that eliminates or reduces contaminants. The usual reference is to reduce potentially harmful or undesirable microorganisms.

disinfectant, *n*—a physical or chemical agent or process that destroys pathogenic or potentially pathogenic microorganisms in/on surfaces or objects.

D-value (decimal reduction time/log death time), *n*—the time or radiation dose required to achieve inactivation of 90 % of one $\log_{10}$ of a population of the test microorganism under stated exposure conditions.

effectiveness, *n*—a measure of the performance of a product.

efficacy, *n*—the proven performance of a product established under defined conditions of testing.

envelope, *n*—a layer of host cell membrane-deprived lipid that surrounds the capsid of some viruses.

false negative, *adj*—incorrectly indicating the absence of a finding or condition.

[1] This terminology 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 May 1, 2010. Published December 2010. DOI: 10.1520/E2756–10.

false positive, *adj*—incorrectly indicating the presence of a finding or condition.

fomite (fomes), *n*—an inanimate object that harbors pathogenic microorganisms and may transmit infection.

germ, *n*—microorganisms pathogenic to humans.

glove juice procedure, *n*—a process requiring placement of test subjects' hands into low bioburden plastic bags or sterile gloves that are powder-free and non-antimicrobial. Stripping solution is added to the glove, the hands are massaged, and the stripping solution (glove juice) is sampled to recover microorganisms.

grab sample, *n*—single sample from process stream (flowing) or from source of confined geometry (stagnant) withdrawn at a specific time.

inoculum, *n*—the viable microorganisms used to contaminate a sample, device, or surface, often expressed as to number and type.

intermediate-level disinfectant, *n*—a disinfectant that inactivates mycobacteria, vegetative bacteria, most fungi, and lipid and non-lipid viruses.

low-level disinfectant, *n*—a disinfectant that inactivates vegetative bacteria, lipid viruses, and some fungi.

minimum inhibitory concentration (MIC), *n*—the lowest concentration of an antimicrobial agent that prevents visible growth of a microorganism in an agar or broth dilution susceptibility test.

negative control, *n*—material or procedure used to differentiate the effects of specified treatments from the uncontrolled variables in a test system.

neutralization, *n*—the process for inactivating or quenching the activity of a microbicide, often achieved through physical (for example, filtration or dilution) or chemical means.

persistent effect, *n*—prolonged antimicrobial activity measured after treatment(s) that prevents or inhibits proliferation or survival of microorganisms, or both.

positive control, *n*—treatment using known material or procedure used to validate a test protocol.

precision, *n*—the closeness of agreement between independent test results obtained under prescribed conditions.

preservative, *n*—chemical agent(s) added to a product to reduce or prevent microbial growth.

recovery control, *n*—a procedure that validates that initial population(s) meet the criterion of a method.

reference control, *n*—material or procedure with known performance in a test method.

repeatability, *n*—the precision of test results obtained in the same laboratory under specifically defined conditions.

reproducibility, *n*—the precision of test results obtained in different laboratories performing the same test procedure under specifically defined conditions.

resident microbial skin flora, *n*—microorganisms that survive and multiply on the skin, forming a stable population.

room temperature, *n*—temperature in the range of 20 to 30°C (68 to 85°F).

sanitizer, *n*—chemical or physical agent(s) used to reduce the number of microorganisms to a level judged to be appropriate for a defined purpose and/or claim.

slimicide, *n*—chemical agent(s) added to a process to reduce the number of slime-forming microorganisms.

sterilant, *n*—chemical or physical agent(s) that kill all forms of microorganisms in the inanimate environment.

surrogate microorganism, *n*—microorganism that is tested to estimate responses of other microorganism(s) for which direct testing is impractical.

transient microbial skin flora, *n*—microorganisms that contaminate the skin but do not form a stable population.

treated materials or articles, *n*—plastic, textile, or other pre-formed articles pretreated with antimicrobial products before first use. The antimicrobial benefit is limited to the material or article to maintain or preserve its chemical and/or physical integrity.

validation, *n*—the action (or process) or proving that a procedure, process, system, equipment, or method works and achieves its intended purpose under defined conditions.

volar aspect of the forearm, *n*—the surface of the forearm on the same side as the palm of the hand.

BIBLIOGRAPHY[2]

[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.

(1) E640 Test Method for Preservatives in Water-Containing Cosmetics
(2) E645 Test Method for Efficacy of Microbicides Used in Cooling Water Systems
(3) E723 Test Method for Efficacy of Antimicrobials as Preservatives for Aqueous-Based Products Used in the Paper Industry (Bacterial Spoilage)
(4) E875 Test Method for Efficacy of Fungal Control Agents as Preservatives for Aqueous-Based Products Used in the Paper Industry
(5) E979 Test Method for Evaluation of Antimicrobial Agents as Preservatives for Invert Emulsion and Other Water Containing Hydraulic Fluids
(6) E1052 Test Method for Efficacy of Antimicrobial Agents Against Viruses in Suspension
(7) E1053 Test Method for Efficacy of Virucidal Agents Intended for Inanimate Environmental Surfaces
(8) E1054 Test Methods for Evaluation of Inactivators of Antimicrobial Agents
(9) E1115 Test Method for Evaluation of Surgical Hand Scrub Formulations
(10) E1153 Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces
(11) E1173 Test Method for Evaluation of Preoperative, Precatheterization, or Preinjection Skin Preparations
(12) E1174 Test Method for Evaluation of the Effectiveness of Health Care Personnel Handwash Formulations
(13) E1259 Practice for Evaluation of Antimicrobials in Liquid Fuels Boiling Below 390°C
(14) E1326 Guide for Evaluating Nonconventional Microbiological Tests Used for Enumerating Bacteria
(15) E1327 Test Method for Evaluation of Antimicrobial Handwash Formulations by Utilizing Fingernail Regions
(16) E1428 Test Method for Evaluating the Performance of Antimicrobials in or on Polymeric Solids Against Staining by *Streptoverticillium reticulum* (A Pink Stain Organism)
(17) E1482 Test Method for Neutralization of Virucidal Agents in Virucidal Efficacy Evaluations
(18) E1589 Test Method for Evaluation of First Aid Antiseptic Drug Products
(19) E1766 Test Method for Determination of Effectiveness of Sterilization Processes for Reusable Medical Devices
(20) E1837 Test Method to Determine Efficacy of Disinfection Processes for Reusable Medical Devices (Simulated Use Test)
(21) E1838 Test Method for Determining the Virus-Eliminating Effectiveness of Hygienic Handwash and Handrub Agents Using the Fingerpads of Adults
(22) E1839 Test Method for Efficacy of Slimicides for the Paper Industry—Bacterial and Fungal Slime
(23) E1874 Test Method for Recovery of Microorganisms from Skin using the Cup Scrub Technique
(24) E1882 Test Method for Evaluation of Antimicrobial Formulations by the Agar Patch Technique
(25) E1883 Test Method for Assessment of an Antibacterial Handwash Product by Multiple Basin Wash Technique
(26) E1891 Guide for Determination of a Survival Curve for Antimicrobial Agents Against Selected Microorganisms and Calculation of a D-Value and Concentration Coefficient
(27) E2011 Test Method for Evaluation of Hygienic Handwash and Handrub Formulations for Virus-Eliminating Activity Using the Entire Hand
(28) E2111 Quantitative Carrier Test Method to Evaluate the Bactericidal, Fungicidal, Mycobactericidal, and Sporicidal Potencies of Liquid Chemical Microbicides
(29) E2149 Test Method for Determining the Antimicrobial Activity of Immobilized Antimicrobial Agents Under Dynamic Contact Conditions
(30) E2180 Test Method for Determining the Activity of Incorporated Antimicrobial Agent(s) In Polymeric or Hydrophobic Materials
(31) E2196 Test Method for Quantification of a *Pseudomonas aeruginosa* Biofilm Grown with Shear and Continuous Flow Using a Rotating Disk Reactor
(32) E2197 Quantitative Disk Carrier Test Method for Determining the Bactericidal, Virucidal, Fungicidal, Mycobactericidal and Sporicidal Activities of Liquid Chemical Germicides
(33) E2274 Test Method for Evaluation of Laundry Sanitizers and Disinfectants
(34) E2275 Practice for Evaluating Water-Miscible Metalworking Fluid Bioresistance and Antimicrobial Pesticide Performance
(35) E2276 Test Method for Determining the Bacteria-Eliminating Effectiveness of Hygienic Handwash and Handrub Agents Using the Fingerpads of Adults
(36) E2314 Test Method for Determination of Effectiveness of Cleaning Processes for Reusable Medical Instruments Using a Microbiologic Method (Simulated Use Test)
(37) E2315 Guide for Assessment of Antimicrobial Activity Using a Time-Kill Procedure
(38) E2361 Guide for Testing Leave-On Products Using In-Situ Methods
(39) E2362 Practice for Evaluation of Pre-saturated or Impregnated Towelettes for Hard Surface Disinfection
(40) E2406 Test Method for Evaluation of Laundry Sanitizers and Disinfectants for Use in High Efficiency Washing Operations
(41) E2471 Test Method for Using Seeded-Agar for the Screening Assessment of Antimicrobial Activity In Carpets
(42) E2562 Test Method for Quantification of *Pseudomonas aeruginosa* Biofilm Grown with High Shear and Continuous Flow using CDC Biofilm Reactor
(43) E2613 Test Method for Determining Fungus-Eliminating Effectiveness of Hygienic Handwash and Handrub Agents Using Fingerpads of Adults
(44) E2614 Guide for Evaluation of Cleanroom Disinfectants
(45) E2647 Test Method for Quantification of a *Pseudomonas aeruginosa* Biofilm Grown Using a Drip Flow Biofilm Reactor with Low Shear and Continuous Flow