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Standard Terminology Relating to Antimicrobial and Antiviral Agents¹

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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.

1.3 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

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).

¹ This terminology 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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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 propagated 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 a heat exchange system.

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.

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*—in microbiology, a specimen comprised of living spores, bacteria, yeast or the multicellular filamentous fungi, or combination of two or more types of microorganisms, that are introduced into a test medium or onto a specimen to be tested in order to investigate the ability of the medium or specimen to support microbial growth or to investigate its antimicrobial properties.

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.