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Standard Test Method to Determine Efficacy of Disinfection Processes for Reusable Medical Devices (Simulated Use Test)[1]

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INTRODUCTION

When special tests designed to register or validate a disinfection process currently are used, the procedures, their statistical considerations (usually all negatives at a given time point), and the physical problems of applying organisms to surfaces, such as sutures and unglazed porcelain carriers, may cause inaccurate and confusing results. Practical, in-use testing of reprocessing techniques and conditions are needed. Exaggerated conditions for testing can be achieved with the use of actual instruments contaminated with high numbers of organisms. The addition of serum as an organic load or hard water minerals as an inorganic load can be made to enhance worst-case conditions. When these elements are coupled with the processing, as actually performed, the result is a structured test that is a simulated-use procedure. This test method is designed to incorporate several elements of reprocessing, including cleaning, rinsing, and disinfection (including optional treatment of the internal channels of devices, such as endoscopes) with a terminal alcohol rinse rather than examining only the effectiveness of the entire disinfection process. A simulated-use test to examine the effectiveness of reprocessing procedures is valuable because several incidents of contamination of instruments in use have been recorded with vegetative cells of bacteria, for example, *Pseudomonas* and the mycobacteria.

When this procedure is performed with a representative mycobacterial culture, it is necessary to use a nonpathogenic strain such as *Mycobacterium terrae* (isolated from soil) that can be manipulated on an open bench. This strain is used in tuberculocidal testing in Europe, and published information shows comparable resistance to antimicrobials as that displayed by human tuberculosis strains of *Mycobacterium tuberculosis.* This organism can be handled easily and grows faster than other test strains, such as *M. bovis.* **(1,2,3,4,** and **5).**[2]

Because contamination of the surfaces of instruments has occurred from rinsing with tap water, bacteria-free water should be used for all rinsing during reprocessing in this test procedure when a water rinse step is part of the reprocessing directions.

1. Scope

1.1 This test method is intended to describe a procedure for testing the effectiveness of a disinfection process for reprocessing reusable medical devices when it is tested with a challenge of vegetative cells including mycobacteria. Disinfection normally deals with testing activity against vegetative cells of bacteria, viruses, and fungi. Since this test method is process oriented, the user may wish to examine a variety of test organisms.

1.2 This test method is designed to provide a reproducible procedure to verify the effectiveness of a previously validated disinfectant or disinfection procedure for reusable medical instruments and devices.

1.3 This test method is not meant to define the effectiveness of or validation of the particular disinfection process used or its kinetics, but rather, it is devised to confirm the effectiveness of the disinfection process by simulating use situations with a particular test process using medical devices and instruments. Either manual or machine reprocessing can be tested.

1.4 This test method is intended for use with reusable cleaned and previously sterilized or disinfected (high level) medical instruments and devices. Endoscopes are described in this test method as a worst-case example for contamination and sampling. The selected sterilization or disinfection processes, or both, should have been validated previously, as well as the effectiveness of rinsing for residual sterilant/disinfectant removal determined.

1.5 An inoculum with high numbers of selected microorganisms is applied to both test and control, cleaned and

[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 Antibacterial Agents.

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

sterilized, or disinfected medical instruments. Strains of microorganisms with a recorded resistance to disinfectants are used to contaminate the instrument sites known or suspected to be the most difficult to reprocess.

1.6 It is impractical to test for recovery of survivors by immersion of some instruments, for example, endoscopes or some laproscopic instruments, in growth medium because of complexity, size, difficulty in long-term incubation, or deterious effects resulting from incubation. Elution of organisms from the inoculated surfaces, therefore, may be performed to estimate the number of recoverable organisms. Immersion can be used for smaller instruments.

1.7 Control instruments are inoculated in the same manner as the test instruments and elution or immersion methods are performed to determine the number of organisms recoverable from the instrument. For channeled devices, such as endoscopes testing, the number of organisms recoverable from the instrument (inside and outside) will serve as the initial control count. It is expected that some fraction of the number of organisms inoculated will be lost in the process of inoculation/drying.

1.8 A testing procedure can be performed on a complete reprocessing cycle or can be limited to just the cleaning or disinfection portions of the cycle whether reprocessing is done in a machine or manually.

1.9 After the test cycle has been completed, remaining inoculated bacteria will be recovered from test instruments using the same elution procedures as for the control instruments.

1.10 Efficacy of a disinfection cycle or reprocessing cycle, or any part thereof, may be determined by comparison of the number of microorganisms recovered from the control instrument (initial recoverable control count) to the recovery determined for the test instruments.

1.11 A knowledge of microbiological techniques is required to conduct these procedures.[3]

1.12 *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:*

E 1054 Practices for Evaluating Inactivators of Antimicrobial Agents Used in Disinfectant, Sanitizer, Antiseptic, or Preserved Products[4]

3. Terminology

3.1 *Definitions:*

3.1.1 *bioburden, n*—the number and type of viable microorganisms that can be recovered from surfaces using standard recovery procedures.

3.1.2 *CFU*—colony forming units.

3.1.3 *disinfectant*—any biocidal chemical that produces materials free from vegetative microorganisms that may contaminate them and potentially cause infection.

3.1.3.1 *Discussion*—The definitions included are the traditional ones. The user may choose to conform to other criteria that specify elimination of a certain number of test microorganisms. Other definitions describe the action as application of a process resulting in elimination of microorganisms. Whatever criteria is selected, it should be stated before initiation of the test procedure.

3.1.3.2 *Discussion*—A series of three definitions devised by Spaulding **(6, 7)** separated the activity of germicides against spores and mycobacteria and non-lipid viruses and are therefore defined by activity against groups of microorganisms. These definitions are as follows:

(1) High-level disinfectants must inactivate bacteria endospores, mycobacteria, non-lipid viruses, fungi, vegetative bacteria, and lipid viruses. If exposure time is extended long enough, this type of germicide can be used as a sterilant.

(2) Medium-level disinfectants inactivate mycobacteria, vegetative bacteria, fungi including asexual spores, and lipid and non-lipid viruses.

(3) Low-level disinfection inactivate vegetative bacteria, most fungi, and lipid viruses.

3.1.4 *disinfector, n*—any device or physical process that provides a biocidal process that produces materials free from vegetative microorganisms that may contaminate them and potentially cause infection.

3.1.5 *inoculum*—the number (usually expressed in colony forming units, cfu) and type (genus and species) of viable microorganisms used to contaminate a given sample or object. Strain identification and the means used to identify the organism should be indicated.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *accessible site, n*—a location on or in a reusable medical instruments that can be contacted by bioburden and disinfectants.

3.2.2 *reusable medical device, n*—any medical instrument that is claimed at manufacture to be usable after reprocessing.

3.2.3 *worst-case, n*—the intentional exaggeration of one or more parameters of test compared to normal condition.

4. Summary of Test Method

4.1 This test method is performed by contamination of accessible, interior, and exterior surfaces of instruments or devices intending to reach the sites identified as the leastaccessible or most difficult to reach sites.

4.2 The number of microorganisms contaminating the test instruments or devices prior to processing is determined by contamination and elution of at least two control unprocessed units (representing a large complex instrument). More control units of smaller instruments may be used. Contamination with an inoculum with high numbers of microorganisms to achieve at least 10^6 cfu/instrument, recoverable is required.

4.3 After inoculation, the test instrument(s) are processed according to the manufacturer's instructions for use of the reprocessing cycle, the disinfectant, or disinfector. Either the disinfectant, disinfector cycle alone, or the disinfectant (disinfector) cycle plus any cleaning, rinsing, or other contributory

[3] CDC-NIH Biosafety in Microbiological and Biomedical Laboratories, 3rd ed., U.S. Department of Health and Human Services, Washington, DC, 1993.

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