Designation: ~~D7225 – 06~~ D7225 – 13

Standard Guide for Blood Cleaning Efficiency of Detergents and Washer-Disinfectors[1]

This standard is issued under the fixed designation D7225; 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 guide is based on a standardized test soil correlating to coagulated blood suitable for screening tests and the evaluation of the cleaning efficiency of washer-disinfectors used for reprocessing of surgical instruments. This guide strictly deals with cleaning and does not describe any methods that are related to disinfection. See the Referenced Documents D5343, D4008, D4265, D4488, D2960, D3050, in Section 2 for additional information.

1.2 The values ~~given~~stated in SI units are to be ~~considered the standard.~~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 to determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

D5343 Guide for Evaluating Cleaning Performance of Ceramic Tile Cleaners

D4008 Test Method for Measuring Anti-Soil Deposition Properties of Laundry Detergents (Not Suitable for Detergent Ranking)

D4265 Guide for Evaluating Stain Removal Performance in Home Laundering

D4488 Guide for Testing Cleaning Performance of Products Intended for Use on Resilient Flooring and Washable Walls (Withdrawn 2009)[3]

D2960 Guide for Controlled Laundering Test Using Naturally Soiled Fabrics and Household Appliances

D3050 Guide for Measuring Soil Removal from Artificially Soiled Fabrics (Not Suitable for Detergent Ranking)

2.2 *AAMI Standards:*[4]

ANSI/AAMI ~~ST35:2003~~ST79 ~~Safe handling and biological decontamination of reusable medical devices~~ Comprehensive guide to steam sterilization and sterility assurance in health care facilities~~ and in nonclinical settings~~

~~ANSI/AAMI ST46:2002~~AAMI TIR 12 ~~Steam sterilization and sterility assurance~~ Designing, testing, and labelling reusable medical devices for reprocessing in health care ~~facilities~~facilities: a guide for medical device manufacturers

ANSI/AAMI ST81 Sterilization of medical devices – information to be provided by the manufacturer for the processing of resterilizable medical devices

AAMI TIR 30 A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices

2.3 *ISO Standards*[5]

ISO 15883–2 Washer-disinfectors, part 2: requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.

ISO/TS 15883–5:2005 Washer-disinfectors, part 5: test soils and methods for demonstrating cleaning efficacy of washer-disinfectors

[1] This guide is under the jurisdiction of ASTM Committee D12 on Soaps and Other Detergents and is the direct responsibility of Subcommittee D12.16 on Hard Surface Cleaning.

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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.

[3] The last approved version of this historical standard is referenced on www.astm.org.

[4] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.

[5] Available from International Organization for Standardization (ISO), 1, ch. de la Voie-Creuse, CP 56, CH-1211 Geneva 20, Switzerland, http://www.iso.org.

3. Summary of Guide

3.1 The standardized test soil is based on a proteinous matrix containing fibrinogen and thrombin in two separated components. Coagulation and formation of fibrin fibers are induced after mixing the two components.

3.2 The suggested methods are based on the removal of standardized test soil as a result of mechanical or chemical action, or both, of the tested detergents or washer-disinfectors, or both. The screening test provides qualitative results for cleaning efficacy. After testing the practical situation in a washer-disinfector, the end result is visually checked for immediate evaluation. Minor residue is detected by using the peroxidase reaction. The quantitative test provides quantitative results for cleaning efficacy by providing measuring the removal of a known amount of protein. After placement of the test coupon within a washer or in a beaker of water, the end result is measured gravimetrically or by spectophotometer detection of protein residue, or both.

4. Significance and Use

4.1 *Significance*—Dried blood represents a significant challenge to cleaning surgical instruments. The water-soluble components of blood are easily rendered insoluble when exposed to heat, chemical solutions, or time at room temperature. The water insoluble component of blood is fibrin built up during coagulation. These proteins bind quite readily to the surfaces of surgical instruments making them difficult to remove even with the aid of chemical cleaning agents. Instruments contaminated with blood residue after reprocessing represent a significant threat for infection to healthcare workers and patients. Healthcare facilities typically employ the use of automated instrument washers. These devices combine mechanical action along with chemical cleaning agents in a staged cleaning cycle designed to thoroughly clean surgical instruments. To function properly, these machines must be performing at targeted mechanical efficiency and deliver the correct chemical cleaning agents at the correct temperature, at the correct dosage for the correct period of time. Manufacturers of automated washers and manufacturers of cleaning detergent need to evaluate the performance of their products utilizing a surrogate for surgical instruments soiled with blood. The results of the performance testing will be used to improve product design and for validation of the performance of their product for various regulatory requirements.

4.2 *Use*—The regular, periodic use of the blood soil test is a systemic challenge to the functioning of an automated washer. To properly challenge the cleaning device, the test must be analogous to ~~both~~ the dried blood ~~soil~~ soil, to the stainless steel substrate, and to the physical barriers presented by surgical instruments. These physical barriers include the box lock, or pivot joint of a hinged instrument, the serrated tips, and crevices of surgical instruments. On the test coupon, the components of blood ~~mimic~~ are similar to the state of dried blood on instruments. By utilizing a grooved stainless steel coupon, the substrate is similar to that of stainless steel instruments. By mounting the soiled coupon in a plastic holder the physical barriers represented by cracks and crevices of instruments (for example, box locks) are ~~mimicked.~~represented. Users are provided with an interpretation guide that aids them in interpreting results that are less than optimal. For instance, failure to remove the fibrin layer of blood soil (which is water insoluble) indicates a problem with the chemical cleaning agent(s). Failure to evenly remove a hemoglobin soil indicates a mechanical failure. Failure to remove any soil indicates either a catastrophic mechanical failure, or inappropriate settings for the initial rinse stage. As a standardized challenge, the test provides a reproducible means for the washer manufacturer and the detergent manufacturer to compare new designs and formulations to those existing within their own product line as well as those of others in the market. For the purpose of submitting their instructions for use, the test provides a means to validate the performance of their product with a device that is a surrogate for the devices their products will be used to clean in the practical setting. This validation testing can be used as part of any necessary documentation for regulatory filings and records.

5. Reagents and Materials

5.1 *Standardized Test Soil*

5.1.1 *Composition:*

5.1.1.1 *Component A:*
400-mg albumine, bovine, protease free;
400-mg hemoglobin, bovine, lyophilized; and
60-mg fibrinogen, bovine, lyophilized.

5.1.1.2 *Component B:*
400-mg albumine, bovine, protease free;
400-mg hemoglobin, bovine, lyophilized; and
12.5-NIH units thrombin, reagent grade from bovine plasma.

5.1.1.3 *Solvent A*—5.0-mL 0.4 % NaCl solution (Reagent grade NaCl dissolved in sterile water).

5.1.1.4 *Solvent B*—5.0-mL 0.4 % NaCl solution + 8.0-mmol/L $CaCl_2$. (Reagent grade NaCl dissolved in sterile water).

5.2 *Preparation*—Components A and B are dissolved in their corresponding Solvents A and B by shaking for 1 h at room temperature (from ~~20°C -~~20 to 37°C) in two sealed 10-mL glass vials. Shaking by hand is acceptable and the most easy/practical solution and is tested to give reliable results. A laboratory quality shaker could be used for a more reproducible process.