



Designation: D7907 – 14 (Reapproved 2019)

Standard Test Methods for Determination of Bactericidal Efficacy on the Surface of Medical Examination Gloves¹

This standard is issued under the fixed designation D7907; 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 methods herein specify two analytical tests for quantitatively evaluating surface bactericidal efficacy of medical examination gloves incorporated with bactericidal properties. They may be used for the determination of bactericidal activity on either the outer or inner glove surface. The methods incorporate bacterial challenges in two different formats: Method (A) a saline or buffered saline solution, and Method (B) a saline or buffered saline solution containing an organic load. Each method represents a different means of microbial contamination that can be expected in the healthcare environment.

1.2 Methods described herein are not appropriate for virucidal, fungicidal, tuberculocidal or sporicidal evaluations as each of these categories require unique culture techniques and testing conditions. Results of the test methods described in this document are limited to bactericidal efficacy against vegetative bacteria.

1.3 A more expansive glove description, such as broad spectrum antimicrobial efficacy, would require testing of a broader list of microbial species than vegetative bacteria alone. It is recommended that interested manufacturers discuss species and strain selections with appropriate regulatory agencies before testing is commenced.

1.4 Testing is to be performed by individuals trained in microbiological techniques under appropriate controlled conditions to ensure integrity of results and personnel safety.

1.5 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.6 *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, health, and environmental practices and deter-*

mine the applicability of regulatory limitations prior to use. Most regulatory agencies require compliance with Biocompatibility guidelines under ISO 10993.

1.7 *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. Referenced Documents

2.1 ASTM Standards:²

[D7160 Practice for Determination of Expiration Dating for Medical Gloves](#)

[E178 Practice for Dealing With Outlying Observations](#)

[E1054 Test Methods for Evaluation of Inactivators of Antimicrobial Agents](#)

2.2 Other References:

[U.S. Pharmacopeia General Notices in U.S. Pharmacopeia 26th rev. Rockville, MD: U.S. Pharmacopeia; 2003. 2nd Supplement](#)

3. Terminology

3.1 Definitions:

3.1.1 *active side, n*—refers to the inside or outside surface of the glove on which the antimicrobial agent has been placed. This may be both sides if the active agent is placed on both the inside and outside surfaces or if the active agent is incorporated during compounding and is expressed onto both surfaces.

3.1.2 *aliquot, n*—a portion of a total amount of a solution or suspension.

3.1.3 *bactericide (or bacteriocide), n*—a substance that kills or destroys bacteria.

3.1.4 *bacteriostat, n*—chemical or biological material that stops the growth (reproduction) of bacteria, but does NOT kill them.

¹ These test methods are under the jurisdiction of ASTM Committee D11 on Rubber and Rubber-like Materials and are the direct responsibility of Subcommittee D11.40 on Consumer Rubber Products.

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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.