



Designation: D7102 – 17 (Reapproved 2022)^{ε1}

Standard Guide for Determination of Endotoxin on Sterile Medical Gloves¹

This standard is issued under the fixed designation D7102; 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.

^{ε1} NOTE—Corrected 2.1 editorially in October 2024.

INTRODUCTION

This guide is established and designed to determine the qualitative or quantitative presence of bacterial endotoxin on sterile medical gloves. Bacterial endotoxins are found in the outer membrane of Gram negative bacteria and may contaminate gloves during the manufacturing process. Consequences of endotoxin introduced into a patient during invasive procedures are dose dependent and may include inflammation, fever, nausea, pain, clot formation, hypoglycemia and reduced perfusion of the heart, kidney, and liver as well as endotoxic shock. Endotoxins are not inactivated by routine methods utilized in the routine sterilization of medical gloves including irradiation (gamma or E-beam), ethylene oxide, or steam.

1. Scope

1.1 This guide covers a selection of methodologies for the determination of bacterial endotoxin on gloves when such a determination is appropriate.

1.2 As bacteria may continue to grow on non-sterile gloves, reportable endotoxin levels are only appropriate for gloves labeled as sterile. Because most environments contain endotoxin, once a box of gloves is opened and the gloves are manipulated, endotoxin levels will increase making it inappropriate to report endotoxin levels on boxed gloves (ex. examination gloves). This is true even if the box had undergone sterilization prior to distribution.

1.3 This guide may also be appropriate for internal quality control or alert purposes at different stages of manufacturing or during process change evaluations.

1.4 This guide is not applicable to the determination of pyrogens other than bacterial endotoxins.

1.5 The sample preparation method described must be used regardless of the test method selected. This method does not describe laboratory test method validation, analyst qualification, or reagent confirmation. Product-specific validation is addressed.

1.6 The safe and proper use of medical gloves is beyond the scope of this guide.

¹ This guide is under the jurisdiction of ASTM Committee D11 on Rubber and Rubber-like Materials and is the direct responsibility of Subcommittee D11.40 on Consumer Rubber Products.

Current edition approved June 1, 2022. Published July 2022. Originally approved in 2004. Last previous edition approved in 2017 as D7102 – 17. DOI: 10.1520/D7102-17R22E01.

1.7 *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 determine the applicability of regulatory limitations prior to use.*

1.8 *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 *EN Standard:*²

EN 455-3:2015 Medical Gloves for Single Use—Part 3: Requirements and Testing for Biological Evaluation

2.2 *ANSI Standard:*³

ANSI/AAMI ST 72:2011 Bacterial Endotoxins—Test Methodologies, Routine Monitoring and Alternatives to Batch Testing

3. Terminology

3.1 *Definitions:*

3.1.1 *bacterial endotoxin test (BET)*—a method for determining the qualitative or quantitative presence of endotoxin in

² Available from European Committee for Standardization (CEN), Avenue Marnix 17, B-1000, Brussels, Belgium, <http://www.cen.eu>.

³ Available from American National Standards Institute (ANSI), 1180 Avenue of the Americas, 10th Floor, New York, NY 10036, <http://www.ansi.org>.