



Designation: F1862/F1862M – 24

Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)¹

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INTRODUCTION

Workers, primarily those in the healthcare profession involved in treating and caring for individuals injured or sick, can be exposed to biological liquids capable of transmitting disease. These diseases, which may be caused by a variety of microorganisms, can pose significant risks to life and health. This is especially true of blood-borne viruses which cause hepatitis (hepatitis B virus (HBV) and hepatitis C virus (HCV)) and acquired immune deficiency syndrome (AIDS) (human immunodeficiency virus (HIV)). Because engineering controls cannot eliminate all possible exposures, attention is placed on reducing the potential of direct skin and mucous membrane contact through the use of protective clothing that resists penetration (29 CFR Part 1910.1030). This test method was developed for assessing the synthetic blood penetration resistance performance of medical face masks in a manner representing actual use as might occur when a high-velocity stream of blood from a punctured artery hits the face mask.

1. Scope

1.1 This test method is used to evaluate the resistance of medical face masks to penetration by the impact of a small volume (~2 mL) of a high-velocity stream of synthetic blood. Medical face mask *pass/fail* determinations are based on visual detection of synthetic blood penetration.

1.2 This test method does not apply to all forms or conditions of blood-borne pathogen exposure. Users of the test method must review modes for face exposure and assess the appropriateness of this test method for their specific application.

1.3 This test method is primarily intended to address the performance of finished medical face masks. While this test method may also be used to assess performance of materials or certain material constructions used in medical face masks, it is important to note the performance of finished medical face masks may be impacted by the interaction of the materials used and how they have been assembled. Results can differ depending on testing a final finished medical face mask or materials taken from manufactured medical face masks.

1.4 This test method does not address other factors with the potential to affect the overall protection offered by the medical face mask and its operation (such as filtration efficiency and pressure drop).

1.5 This test method does not address breathability of the medical face mask materials or any other properties affecting the ease of breathing through the medical face mask. This test method evaluates medical face masks as an item of protective clothing. This test method does not evaluate the performance of medical face masks for airborne exposure pathways or in the prevention of the penetration of aerosolized body fluids deposited on the medical face mask.

1.6 The values stated in SI units or inch-pound units are to be regarded separately as standard. The values stated in each system may not be exact equivalents; therefore, each system shall be used independently of the other. Combining values from the two systems may result in nonconformance with the standard. The pressure values stated in each system are not exact equivalents. However, as the corresponding velocities are within 1 % of each other (see X1.4.2), reporting of the results in either units is permitted.

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 This test method is under the jurisdiction of ASTM Committee F23 on Personal Protective Clothing and Equipment and is the direct responsibility of Subcommittee F23.40 on Biological.

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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 ASTM Standards:²

D891 Test Methods for Specific Gravity, Apparent, of Liquid Industrial Chemicals

D1331 Test Methods for Surface and Interfacial Tension of Solutions of Paints, Solvents, Solutions of Surface-Active Agents, and Related Materials

E171/E171M Practice for Conditioning and Testing Flexible Barrier Packaging

F1494 Terminology Relating to Protective Clothing

F1670/F1670M Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood

F1671/F1671M Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System

F2100 Specification for Performance of Materials Used in Medical Face Masks

2.2 ANSI/ASQC Standards:³

ANSI/ASQC Z1.4 Sampling Procedures and Tables for Inspection by Attributes

ANSI/ASQC Q3 Sampling Procedures and Tables for Inspection of Isolated Lots by Attributes

2.3 ISO Standards:⁴

ISO 28590 Sampling Procedures for Inspection by Attributes—Introduction to the ISO 2859 Series of Standards for Sampling for Inspection by Attributes

ISO 2859-1 Sampling Plans for Inspection by Attributes

ISO/TR 8550-1 Guidance on the Selection and Usage of Acceptance Sampling Systems for Inspection of Discrete Items in Lots—Part 1: Acceptance Sampling

ISO/TR 8550-2 Guidance on the Selection and Usage of Acceptance Sampling Systems for Inspection of Discrete Items in Lots—Part 2: Sampling by Attributes

2.4 OSHA Standard:⁵

29 CFR Part 1910.1030 Occupational Exposure to Blood-borne Pathogens: Final Rule, *Federal Register*, Vol 56, No 235, Dec. 6, 1991, pp. 64175–64182

3. Terminology

3.1 Definitions:

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 Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203.

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

⁵ Available from Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

3.1.1 *aerosolized body fluids, n*—body fluids that have been dispersed into air as very small liquid droplets.

3.1.2 *airborne exposure pathways, n*—inhalation routes of exposure to the medical face mask wearer.

3.1.3 *blood-borne pathogen, n*—an infectious bacterium or virus, or other disease-inducing microbe carried in blood or other potentially infectious body fluids.

3.1.4 *body fluid, n*—any liquid produced, secreted, or excreted by the human body.

3.1.4.1 *Discussion*—In this test method, body fluids include liquids potentially infected with blood-borne pathogens, including, but not limited to, blood, semen, vaginal secretions, cerebrospinal fluid, synovial fluid and peritoneal fluid, amniotic fluid, saliva in dental procedures, and any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids (see 29 CFR Part 1910.1030).

3.1.5 *body fluid simulant, n*—a liquid that is used to act as a model for human body fluids.

3.1.6 *medical face mask, n*—an item of protective clothing designed to protect portions of the wearer's face, including the mucous membrane areas of the wearer's nose and mouth, from contact with blood and other body fluids during medical procedures.

3.1.7 *penetration, n*—for biological protective clothing, the flow of a body fluid on a non-molecular level through closures, porous materials, seams, and pinholes, or other imperfections in protective clothing.

3.1.7.1 *Discussion*—In this test method, the penetration liquid is synthetic blood, a body fluid simulant.

3.1.8 *protective clothing, n*—an item of clothing that is specifically designed and constructed for the intended purpose of isolating all or part of the body from a potential hazard; or, isolating the external environment from contamination by the wearer of the clothing.

3.1.8.1 *Discussion*—In this test method, medical face masks are evaluated. The potential hazard of contact with blood or other body fluids is being simulated.

3.1.9 *spurt, n*—a short duration gush or volume of fluid.

3.1.9.1 *Discussion*—In this test method, a spurt refers to the volume of fluid disbursed from the apparatus at the sample mask. It can also refer to the volume of fluid ejected from a punctured blood vessel.

3.1.10 *synthetic blood, n*—a mixture of a red dye/surfactant, thickening agent, and distilled water having a surface tension and viscosity representative of blood and some other body fluids, and the color of blood.

3.1.10.1 *Discussion*—The synthetic blood in this test method does not simulate all of the characteristics of blood or body fluids, for example, polarity (wetting characteristics), coagulation, and content of cell matter.

3.1.11 For definitions of other protective clothing-related terms used in this test method, refer to Terminology **F1494**.

4. Summary of Test Method

4.1 A volume of synthetic blood is disbursed at a specimen mask from a set distance to simulate the impact (splatter) of