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Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood Using a Mechanical Pressure Technique[1]

This standard is issued under the fixed designation F1819; 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.

INTRODUCTION

Workers, primarily those in the ~~health care~~ 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 Viruses~~acquired immune deficiency syndrome (AIDS) (human immunodeficiency viruses (HIV)). Since engineering controls cannot eliminate all possible exposures, attention is placed on reducing the potential for direct skin contact through the use of protective clothing that resists penetration (29 CFR Part 1910.1030). This test method was developed to help assess the effectiveness of materials used in protective clothing for protecting the wearer against contact with body fluids that potentially contain blood-borne pathogens. Using synthetic blood, this test method is intended to determine the amount of mechanical pressure that will cause penetration of a liquid through a material used in protective clothing.

1. Scope

1.1 This test method is used to evaluate the resistance of materials used in protective clothing to synthetic blood under the conditions of liquid contact and increasing direct mechanical pressure. The penetration resistance of protective clothing is based on visual detection of synthetic blood penetration at a specific applied mechanical pressure.

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 work/clothing exposure and assess the appropriateness of this test method for their specific application.

1.3 This test method addresses only the performance of materials or certain material constructions (for example, seams) used in protective clothing. This test method does not address the design, overall construction, components, or interfaces of garments, or other factors which may affect the overall protection offered by the protective clothing.

1.4 The values in SI units or in other units shall be regarded separately as standard. The values stated in each system must be used independently of the other, without combining values in any way.

1.5 *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~~ safety, health, and ~~health~~environmental practices and determine the applicability of regulatory limitations prior to use.*

1.6 *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.*

[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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2. Referenced Documents

2.1 *ASTM Standards:*[2]

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

D1777 Test Method for Thickness of Textile Materials

~~D3776~~D3776/D3776M Test Methods for Mass Per Unit Area (Weight) of Fabric

E105 Practice for Probability Sampling of Materials

~~E171~~E171/E171M Practice for Conditioning and Testing Flexible Barrier Packaging

E691 Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method

F1494 Terminology Relating to Protective Clothing

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

~~F1671~~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

2.2 *ANSI/ASQC Standards:*[3]

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

2.3 *ISO Standard:*[4]

ISO 2859-1 Sampling Plans for Inspection by Attributes

2.4 *Military Standard:*[5]

MIL-STD-105 Sampling Procedures and Tables for Inspection by Attributes

2.5 *OSHA Standard:*[6]

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

3. Terminology

3.1 *Definitions:*

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

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

[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, http://www.asq.org.

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

[5] Available from Standardization Documents Order Desk, DODSSP, Bldg. 4, Section D, 700 Robbins Ave., Philadelphia, PA 19111-5098, http://dodssp.daps.dla.mil.

[6] Available from U.S. Government Printing Office Superintendent of Documents, 732 N. Capitol St., NW, Mail Stop: SDE, Washington, DC 20401, http://www.access.gpo.gov.

3.1.2.1 *Discussion—*

In this test method, body fluids include those liquids potentially infected with blood-borne pathogens, including, but not limited ~~to,~~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).

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

3.1.4 *hydrostatic pressure, n*—the force exerted by a static liquid (**1**).[7]

3.1.5 *mechanical pressure, n*—the force exerted by one solid object upon another that it is touching (**1**).

3.1.6 *penetration, n*—the movement of matter through closures, porous materials, seams, and pinholes or other imperfections in protective clothing on a nonmolecular level.

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

3.1.6.1 *Discussion—*

For this test method, the specific matter is synthetic blood.

3.1.7 *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.

3.1.7.1 *Discussion*—

In this test method, the potential hazard of contact with blood or other body fluids is simulated.

3.1.8 *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.

3.1.8.1 *Discussion*—

The synthetic blood in this test method does not simulate all of the characteristics of real blood or body fluids, for example, polarity (a wetting characteristic), coagulation, content of cell matter.

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

4. Summary of Test Method

4.1 Using a special test apparatus, a specimen is contacted with synthetic blood under a continuously increasing mechanical pressure until the synthetic blood penetrates the specimen or a load of 90.7 kg (200 ~~lbs)~~lb) is applied to a 57.2 mm (2.25 in.) diameter portion of the specimen achieving a pressure on the tested specimen of 345 kPa (50 psig).

4.2 The specimen's non-contact side is observed to determine if visual penetration occurs, and if so, at what mechanical pressure the penetration occurs.

4.3 In conducting a test, the cover plate containing a test head is locked on the two side supports of the base plate of the test apparatus, the multi-position switch is turned to the ~~manual up~~MANUAL UP position, and the test button on top of the control box is held down until visible penetration of the test specimen by synthetic blood is observed through the circular test head. Releasing the button stops the drive motor, and the penetration pressure is shown digitally on the display unit and recorded by the technician.

5. Significance and Use

5.1 This test method was modeled after a procedure commonly known as the Elbow Lean Test.[8] The Elbow Lean Test involves the application of synthetic blood to an ink pad, placement of sample fabric over the ~~blood-soaked~~ blood-soaked pad, placement of a blotter over the sample fabric, and applying elbow or fingertip pressure on top of the blotter. The blotter is then examined for staining as evidence of blood penetration. This test method provides similar procedures which standardize the test equipment and application of pressure through an adopted methodology.

5.2 This test method is intended to simulate actual use conditions wherein areas of the ~~health care~~ healthcare worker's protective clothing are soaked with blood and compressed between the patient's body and that of the ~~health care~~ healthcare worker, or similarly between the ~~health care~~ healthcare worker and instruments. In both cases, unconfined blood can move away from the pressure point taking the path of least resistance rather than being contained as in Test Methods ~~F1670~~F1670/F1670M and ~~F1671~~F1671/F1671M.

5.3 This test method uses predominately mechanical pressure as opposed to contained, hydrostatic pressure to demonstrate liquid penetration resistance (**1, 2**). It simulates a single insult in which the outer surfaces of a protective clothing item are compressed at a steady rate by the wearer's body against a wet surface. This steady rate of compression represents one potential use scenario. Other scenarios may result in a wide variety of pressure ramp rates and profiles that are not simulated by the test apparatus.

5.4 Because this test method provides quantitative results, it is useful for discriminating differences in the liquid barrier performance of protective clothing materials. This test method can be used for measuring differences in the penetration pressure for protective clothing materials which do not pass Test Method ~~F1670~~F1670/F1670M.

5.5 This test method is normally used to evaluate specimens from individual finished items of protective clothing and individual samples of materials that are candidates for items of protective clothing.

5.5.1 Finished items of protective clothing include gloves, arm shields, aprons, gowns, hoods, and boots.

5.5.2 The phrase ~~specimens~~'specimens from finished ~~items~~items' encompasses seamed and other discontinuous regions, as well as the usual continuous regions of protective clothing items.

[8] Originally developed by ~~W.L.Gore and Assoc.,~~W. L. Gore and Assoc. Inc., Elkton, MD 21921.

5.6 Medical protective clothing materials are intended to be a barrier to blood, body fluids, and other potentially infectious materials. Many factors can affect the wetting and penetration characteristics of body fluids, such as surface tension, viscosity, and polarity of the fluid, as well as the structure and relative hydrophilicity or hydrophobicity of the materials. The synthetic blood solution may exhibit different wetting behavior on fabrics or films with identical structures but different chemical compositions. The surface tension range for blood and body fluids (excluding saliva) is approximately 0.042 to 0.060 N/m **(3)**. To help simulate the wetting characteristics of blood and body fluids, the surface tension of the synthetic blood is adjusted to approximate the lower end of this surface tension range. The resulting surface tension of the synthetic blood is 0.042 ± 0.002 N/m.

5.7 The synthetic blood mixture is prepared with a red dye to aid in visual detection and a thickening agent to simulate the flow characteristics of blood. The synthetic blood may not duplicate the polarity, and thus wetting behavior and subsequent penetration, of real blood and other body fluids through protective clothing materials.

5.8 It is known that body fluids penetrating protective clothing materials are likely to carry microbiological contaminants; however, visual detection methods are not sensitive enough to detect minute amounts of liquid containing microorganisms **(~~4~~4-6~~,~~ ~~5, 6~~)**. No viral resistance claims can be made based on this test method, as materials can pass this test method and fail Test Method ~~F1671~~F1671/F1671M.

5.9 Part of the protocol for exposing the protective clothing material specimens to synthetic blood involves applying mechanical pressure up to 345 kPa (50 psig). This mechanical pressure has been documented to discriminate protective clothing material performance and correlate with visual penetration results that are obtained with one type of human factors validation, the Elbow Lean Test.[1] The Elbow Lean Test does not simulate all of the possible types of clinical exposure, as there is one contact with liquid under high mechanical pressure for a short duration. Some studies suggest that mechanical pressures exceeding 345 kPa (50 psig) can occur during clinical use **(7, 8)**.

NOTE 1—The mechanical pressure tester can be adjusted to evaluate materials at higher pressures.

5.10 Testing prior to degradation by physical, chemical, and thermal stresses which could negatively impact the performance of the protective ~~barrier,~~barrier could lead to a false sense of security. Consider tests which assess the impact of storage conditions and shelf life for disposable products, and the effects of laundering and sterilization for reusable products. The integrity of the protective clothing can also be compromised during use by such effects as flexing and abrasion **(9)**. It is also possible that ~~prewetting~~pre-wetting by contaminants such as alcohol and perspiration can compromise the integrity of the protective clothing. Furthermore, high relative humidity may also affect the resistance of materials used in protective clothing to penetration by blood and other body fluids. If these conditions are of concern, evaluate the performance of protective clothing for synthetic blood penetration following an appropriate pretreatment technique representative of the expected conditions of use.

5.11 This test method involves a quantitative determination of a protective clothing penetration resistance to synthetic blood under specific test conditions. It can also be used as a qualitative method for comparing the penetration resistance characteristics of similar materials and as a material quality control or assurance procedure.

5.12 If this test method is used for quality control, perform proper statistical design and analysis of larger data sets where more than three specimens are tested. This type of analysis includes, but is not limited to, reporting the number of individual specimens tested and the average penetration pressure of specimens with a standard deviation. Data reported in this way helps establish confidence limits concerning product performance. Examples of acceptable sampling plans are found in references such as MIL-STD-105, ANSI/ASQC Z1.4, and ISO ~~2859–1.~~2859-1.

5.13 In the case of a dispute arising from differences in reported results when using this test method for acceptance testing of commercial shipments, the purchaser and the supplier should conduct comparative tests to determine if there is a statistical bias between their laboratories. Competent statistical assistance is recommended for investigation of bias. As a minimum, the two parties should take a group of test specimens which are as homogeneous as possible and which are from a lot of the product of the type in question. The test specimens should then be randomly assigned in equal numbers to each laboratory for testing. The average results from the two laboratories should be compared using a non-parametric test for unpaired data and an acceptable probability level chosen by the two parties before testing is begun. If a bias is found, either its cause must be found and corrected or the purchaser and the supplier must agree to interpret future test results with consideration to the known bias.

6. Apparatus

6.1 *Thickness Gauge,* suitable for measuring thickness to the nearest 0.02 mm (0.001 ~~in.),~~in.) in accordance with Test Method D1777, used to determine the thickness of each protective clothing material specimen tested.

6.2 *Mechanical Penetration Tester,*[9,10] shown in Fig. 1, consisting of a base plate, a variable speed drive motor, a belted ~~gear driven~~ gear-driven screw, a lower platform, load cell, upper platform, cover plate, control box, and display unit. The driver motor

[9] The sole source of supply of the apparatus known to the committee at this time is Johnson, Moen & Co., 2505 Northridge Lane NE, Rochester, MN 55906.

[10] The supplier named is the sole source of supply known to the committee at this time. If you are aware of alternative suppliers, please provide this information to ASTM Headquarters. Your comments will receive careful consideration at a meeting of the responsible technical committee,[1] which you may attend.

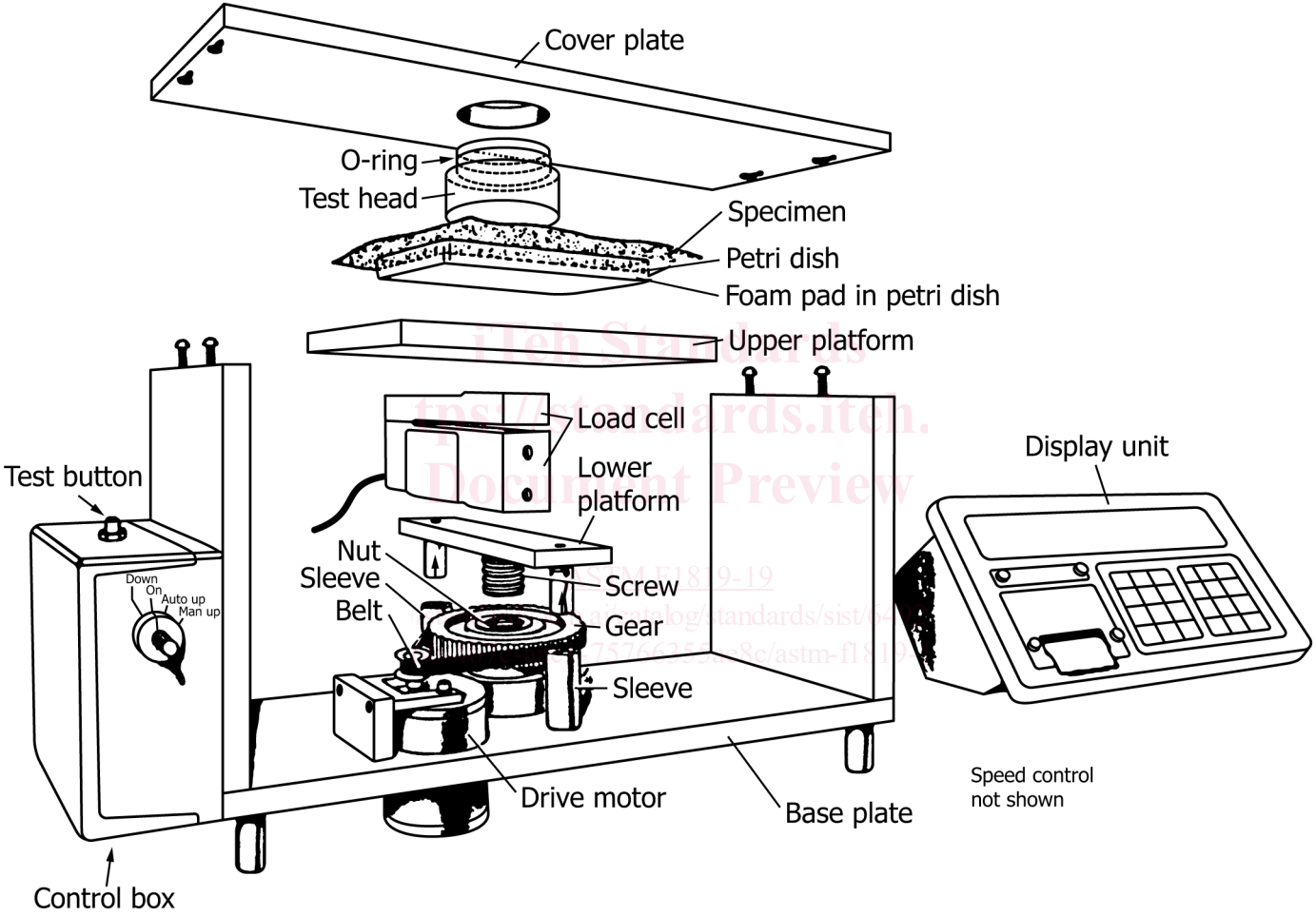

FIG. 1 Mechanical Penetration Tester

is connected to the screw through a belted gear. The screw is then connected to the underside of the lower platform which moves up and down, in tubular sleeves when the screw turns at a rate of 827.5 RPM which corresponds to a platform vertical speed of ~~± 0.20~~ ±0.20 mm/min (0.479 ± 0.008 in./min). The top of the lower platform is fastened to the bottom of the load cell, and the top of the load cell is fastened to the underside of the upper platform. The upper platform provides a location for resting the petri dish containing a foam pad and synthetic blood and the specimen. The control box has a test button and multi-position switch with settings for ~~down, off, auto up.~~DOWN, OFF, AUTO UP, and ~~manual up.~~MANUAL UP. A display unit indicates the load (weight) from the load cell in ~~lbs.~~lb.

NOTE 2—If desired, the rate of compression may be adjusted higher or lower. This may slightly alter the rate of pressure change in the ~~low pressure~~ low-pressure region of the pressure profile (during sponge compression), but will not significantly alter the rate of pressure change in the ~~high pressure~~ high-pressure region of the pressure profile (above sponge compression).

6.2.1 Since small differences in the screw and control box may exist between different mechanical pressure testers, ensure that the platform moves at a speed of 12.17 ± 0.20 mm/min (0.479 ± 0.008 ~~in/min).~~in./min).

6.3 *Circular Test Head,* transparent, with a diameter of ~~57.2 mm~~ 57.2 mm (2.25 in.) and a surface area of 2570 mm^2 (3.976 $in.^2$).

6.4 *Petri Dish,* plastic, 93 by 93 by 15 mm.

6.5 *Foam Pad,* polyester, 0.64 mm (0.25 in.) thick, non-reticulated, with 90 pores/in., a compression ration of 3:1, and free of surfactants and other additives, cut to fit the petri dish dimensions.[11,10]

6.6 *Rod,* poly (methyl methacrylate) (PMMA), approximately 2.5 mm in diameter by 300 mm in length, for saturating the foam pads with synthetic blood and removing air bubbles.

6.7 *Bubble Level,* for leveling instrument.

6.8 *Ruler,* graduated in ~~1 mm (0.05 in.)~~ 1-mm (0.05-in.) increments, for measuring the height of the synthetic blood in the petri dish.

7. Reagents

7.1 *Synthetic Blood*[12,10]—If synthetic blood is not purchased, prepare using following ingredients:

7.1.1 *High Performance Liquid Chromatography ~~(HPLC),~~(HPLC)* quality distilled water (1.0 L, pH 7.0 ± ~~0.5)~~ 0.5).

7.1.2 *Acrysol G111 Thickening ~~agent,~~Agent,*[12,10] ~~25.0~~ 50.0 g.

7.1.3 *Red ~~dye~~Dye*[12,10] containing colorant and surfactant, ~~10.0 g.~~10.0 g.

7.1.4 To reduce biological contamination, boil the distilled water for 5 min and allow to cool to room temperature before mixing. Measure amount of distilled water at ~~20°C (±1°C)~~20 °C (±1 °C) after boiling.

7.1.5 Add the thickening agent to the distilled water and mix 45 min at room temperature on a magnetic stirring plate.

7.1.6 Add the red dye and mix 1 h or more.

NOTE 3—The red dye will stain skin, clothes, and work surfaces.

7.1.7 ~~Determine~~Measure the ~~corrected~~ surface tension of the solution using Test Method D1331~~. The expected value of the corrected surface tension is 0.042 ± 0.002 N/m. Do not use synthetic blood solutions unless within the specified range of~~ , DuNouy ring (Method A). The surface tension measurement declines over time in an undisturbed dish. After filling the sample container using the mixing method in 7.1.9~~surface tension.~~, let the solution sit for 20 min before beginning the surface tension measurement procedure. The surface tension, measured by ring after 20 min, shall be 40 ± 5 dyn/cm.

7.1.7.1 An alternate check of surface tension may be performed with a capillary tube. The expected surface tension in a capillary tube is 61 ± 1 dyn/cm and is not significantly affected by time.[13] Do not use synthetic blood solutions unless within the specified range of surface tension.

NOTE 4—Exposure to atmosphere causes the difference in surface tension between the ring and capillary methods. Because the ring method exposes the synthetic blood to the atmosphere, the surface tension declines rapidly until reaching equilibrium. In contrast, the capillary method protects the synthetic blood from the atmosphere which provides an elevated but stable measurement. Both the ring and capillary methods are acceptable to validate the fluid for testing.

7.1.7.2 ~~The amount of surfactant~~ Excessive oil in the red dye ~~may vary significantly causing unacceptable surface tension variability from batch to batch. If the corrected surface tension is too high, discard the batch of prepared synthetic blood. If the corrected surface tension is too low, remove excess surfactant~~generally causes the unacceptable variations in synthetic blood surface tension. Remove excess oil from the red dye by mixing 25 g of red dye with 1 L of 90 % isopropanol, decant 80 % of the tainted alcohol, and discard or save for distillation. Pour dye-alcohol solution ~~into an~~ onto evaporation dish, spread thin, and cover with filter paper to allow residual alcohol to completely evaporate. The red dye is ready for use when dry.

[11] A suitable pad is a Foamex Product #3-900C custom felt, polyester, beige color foam for medical end use. Foam pads are available from Johnson, Moen & Co., 2505 Northridge Lane NE, Rochester, MN 55906.

[12] Prepared synthetic blood meeting this specification, and small quantities of Direct Red 081, CI #28160 (Morfast Red ~~8BL), and Acrysol G110~~ 8BL) are available from ~~Johnson, Moen & Co., 2505 Northridge Lane NE, Rochester, MN 55906.~~ JM & Co., 507-208-6390.

[13] The capillary tube may be purchased from Fisher Scientific, Catalog #14-818, and the instructions and calculations are specified in the instruction manual.